

## SPECIAL ISSUE

# Neurofeedback Impact on Chronic Headache, Sleep, and Attention Disorders Experienced by Veterans with Mild Traumatic Brain Injury: A Pilot Study

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*A good number of veterans while serving in recent combat zones experienced blast injuries resulting in traumatic brain injuries (TBIs), 80% of which were mild (m) with 25%–50% having prolonged postconcussive symptoms (PCSs). Neurofeedback (NFB) has demonstrated a decent degree of efficacy with mTBI PCSs in civilian and veteran populations. Using infra-low frequency NFB, the authors conducted a pilot study to determine the feasibility and initial efficacy with veterans. Because these results were promising, funding for a full clinical trial was subsequently applied for and acquired.*

Veterans, while serving in Iraq and Afghanistan, may have had exposure to improvised explosive devices (IEDs). These blast exposures resulted in the signature injury (Hayward, 2008) of these operations, the traumatic brain injury (TBI). The overpressurization shock waves emitted from the blast cause what may be considered a mixed mechanism injury event in the brain, involving both a focal (direct impact of brain's surface on the bony protuberances of the skull) and a diffuse injury (stretching and twisting of axons and blood vessels by shearing forces; Chapman & Diaz-Arrastia, 2014). This blast event injury generally generates a secondary, longer duration injury related to the activation of molecular and biochemical responses.

The secondary injury was once thought of as self-limiting (i.e., lasting hours or days postinjury); however, recent findings suggest that the abnormal brain signaling and inflammatory processes last much longer and can lead to long-term symptoms (Chapman & Diaz-Arrastia, 2014). In addition, these dysfunctions can cause disruptions of normal brain connectivity (Hayes, Bigler, & Verfaellie, 2016) and electrical brain waves and patterns, as well as disruptions of intra- and interhemispheric communication, which can persist in many individuals (Taber, Warden, & Hurley, 2006). The changes in the brain stemming from

TBI may persist and even progress in the long run. Evidence has confirmed the long-suspected association between TBI and the development of neurodegenerative diseases later in life (McKee & Robinson, 2014).

The prevalence rate of TBI for service members involved in recent military operations is estimated to be 20% (Chapman & Diaz-Arrastia, 2014; Swanson et al., 2017) with about 80% of these injuries considered mild (mTBI; Chapman & Diaz-Arrastia, 2014). Furthermore, approximately 25%–50% of those with mTBI experience post-concussive symptoms (PCSs) that continue for years (Dean et al., 2012). These PCSs include headaches (Couch & Stewart, 2016; Dean et al., 2012; Hoge et al., 2008), sleep problems (Ayalon et al., 2007; Grima et al., 2016) and cognitive dysfunction, specifically, taking longer to think (Dean et al., 2012), reduced attention (Cooper et al., 2010), impaired working memory, (Dean & Sterr, 2013) and slowed reaction time (Kontos et al., 2013).

Because of the longevity and severity of PCSs, development and implementation of strategies to reduce these symptoms is of critical importance. Veterans diagnosed with mTBI and experiencing PCSs represent treatment challenges to the healthcare system as a result of limited or suboptimal treatment options (Hoge et al., 2008; Institute of Medicine, 2011; Koski et al., 2014).

Rather than a symptom management approach, DeFina and colleagues (2009) described the possibilities of brain repair in TBI by treatments that would enhance neuroplasticity. Neurofeedback (NFB) has been demonstrated to influence cortical neuroplasticity significantly (Enriquez-Geppart et al., 2013; Ros et al., 2013) that can lead to actual and meaningful microstructural changes in white and gray matter (Ghaziri et al., 2013). NFB also has been shown to contribute to neuronal rehabilitation by changing connectivities of specific areas of the brain that may have been impaired, and these rehabilitative changes appear to be

permanent (Ibric et al., 2009). Functional magnetic resonance imaging (fMRI) studies further validate that NFB may be useful in promoting recovery from neurological disorders that are linked to abnormal patterns of brain connectivity (Haller et al., 2013; Koush et al., 2013). Hence, this noninvasive and nonpharmacological method may be used to normalize abnormal network activity by manipulating and strengthening region-specific brain networks (Haller et al., 2013).

Determining if NFB would work for veterans who have been suffering with PCSs was a high priority for us. Prior to conducting a randomized, controlled trial, we designed a pilot project to determine feasibility and provide initial findings of effectiveness. This is a report of the NFB pilot project's findings.

## Background

There are numerous types of conventional NFB approaches with very specific protocols grouped under the general umbrella of NFB. These include but are not limited to Alpha-Theta, Quantitative (Q)-EEG-guided training, Z-Score training, Functional Near Infra-Red Spectroscopy, fMRI, sensorimotor rhythm/Beta (also known as contingency NFB) training, and slow cortical potentials training (Arns & Kenemans, 2014; Larsen & Sherlin, 2013; Othmer, 2020). These different NFB approaches often use dissimilar intervention foci (Othmer, 2020), which may result in different outcomes. NFB has been used since the 1960s for symptoms related to mTBI. According to Duff (2004), studies using NFB (e.g., EEG biofeedback or neurotherapy) indicated that individuals can be taught to promote normal functioning in brains with excessively slow wave activity, which is often found in postconcussive syndrome. In a 2013 review of the literature, May, Benson, Balon, and Boutros used a 10-level classification rubric (10 being the highest level of rigor—e.g., randomized control trials—to 1 being the lowest level—e.g., case study/anecdotal evidence) to classify the research literature of NFB and mTBI. They found two studies at Level 5 (randomized waitlist or intention to treat), six studies at Level 3 (historical control), 10 studies at Level 2 (no control group) and five studies at Level 1 (case study/anecdotal evidence). In the 23 studies reviewed, all reported positive outcomes (i.e., improvements in attention, memory, quality of life, sleep, motor control, coordination, depression and headaches, and self-report of mTBI symptoms). After a thorough meta-analysis of NFB research, Larsen and Sherlin (2013) rated NFB as “probably” efficacious for the treatment of mTBI symp-

toms, despite a lack of randomized controlled trials with a large enough sample to obtain power.

NFB also demonstrated effectiveness in treating symptoms related to mTBI in a sizable number of case reports and research studies. Arns and Kenemans (2014) reported that NFB is associated with improved sleep quality and sleep onset among studies of attention and sleep disorders. In a control group/waitlist study, 60 mTBI participants (aged 18–49 years old) reported improved quality of life after receiving 20 sessions of NFB (Reddy et al., 2014). Munivenkatappa et al. (2014) provided further validation of the ability of NFB to enhance structural and functional connectivity and cognitive scores of individuals who experienced an mTBI.

Only a few studies evaluating NFB among veterans with mTBI have been completed. Nelson and Esty (2012) found that neurotherapy, employed with veterans who participated in Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) who were diagnosed with TBI and posttraumatic stress disorder (PTSD), significantly reduced depression as well as somatic and memory/attention symptoms. Another study demonstrated that NFB was able to enhance quality of life and perceived control in 29 service members with mTBI and PTSD (Strang & Chae, 2013).

Given the prevalence rate of mTBI and subsequent PCSs among veterans as well as the negative effect on well-being and the demonstrated success of NFB, continued research in this area is warranted. The overall objective of this study was to conduct a pilot project within 1 year to ascertain the feasibility of conducting a randomized, controlled trial in a Veteran Administration (VA) setting. Successful feasibility metrics included purchasing equipment and supplies, obtaining Institutional Review Board approval, marketing, recruiting, and completing a course of 20 treatment sessions in the time allowed with no dropouts. In addition to determining feasibility, this pilot study's objective was to evaluate NFB training as a low risk, noninvasive, effective treatment for veterans who sustained an mTBI while serving in the military. It was hypothesized that after NFB training, participants will experience a clinically significant (a) reduction in the frequency and/or severity of headaches; (b) decreased severity of insomnia and/or enhanced perceptions of sleep; (c) improved attention; (d) improved perceptions of quality of life; and (e) decreased levels of self-reported PTSD, depression, distress, and general symptoms. Furthermore, successful completion of the study would support feasibility of NFB implementation in a VA facility located in the Pacific region.

## Method

### *Recruitment Procedures*

The project was reviewed and approved by the local VA IRB, and all participants underwent informed consent. Eligible veterans were between the ages of 18–60; had a comprehensive mTBI evaluation with a confirmed diagnosis of mTBI received while in theater; reported chronic headache, sleep, and attention issues; were not pregnant; could read and write English; and could follow directions. Recruitment involved IRB-approved flyer distribution and presentations to veteran groups about the study.

### *Infra-Low Frequency Neurofeedback*

This pilot study used a nonconventional type of NFB referred to as infra-low frequency (ILF) NFB over a 10-week period. ILF NFB was first developed in 2006 and was further refined in 2017 and 2019 (Othmer & Othmer, 2020). ILF NFB primarily utilizes the Slow Cortical Potential domain, which refers to frequencies below 0.1 Hz (Othmer & Othmer, 2020). Cygnet NFB equipment (<http://www.beemedic.com/cygnet.html>) was used because it has the ILF capability to access brain-wave frequencies as low as .0001. ILF NFB exploits latent neuroplasticity by way of feeding back real-time information on the time course of the frequency-delimited Slow Cortical Potential, as derived from the differential signal from two cortical sites (bipolar montage). This reveals the status of critical linkages within the intrinsic connectivity networks, and on that basis the cerebrum adjusts its activity level, moderates neuronal excitability, and alters connectivity relationships (Othmer & Othmer, 2020; Othmer et al., 2013). As with other conventional types of NFB, ILF NFB also utilizes the standard EEG spectrum, cueing the brain with respect to excursions into dysregulation in particular frequency bands with what is called inhibit-based training. No active inhibition is involved; rather, the process is one of associative learning. In contrast to conventional NFB, ILF NFB does not directly reinforce activity in specific frequency bands (by way of standard operant conditioning procedures). Instead, the entire process is one of endogenous neuromodulation, in which the brain reacts to the information provided on its existing state (Othmer et al., 2013). The use of narrow-band frequency filtering allows the training process to focus specifically on the optimal response frequency, and to do so with a limited noise bandwidth (Wiedemann, 2016). The training process draws attention to the dynamics of the regulatory process that is being organized at the particular frequency. This process is being actively

managed by the brain, and the addition of the external feedback loop simply augments the information on which the brain can act going forward. The result of the process over time is the improved self-regulatory competence of the brain as a learned response (Othmer & Othmer, 2016). There are several publications on the efficacy of ILF NFB in clinical settings (Benson & LaDou, 2016; Dahl, 2020; Grin-Yatsenko et al., 2018; Grin-Yatsenko & Kropotov, 2020; Legarda, 2020; Legarda et al., 2011; McMahan, 2020; Othmer & Othmer, 2009; Shapero & Prager, 2020), but there have been no published formal research studies with sham or blinded control procedures.

The Othmer protocol (2019) was used for participants in this study who experienced mTBI. Two channels and four silver electrodes (1 ground, 2 active, and 1 reference for both active via the use of a jumper cable) were utilized. The ground was placed on the upper mid-forehead, and the reference for both active electrodes was placed at the CZ site on the 10-20 brain mapping system. Using the standardized EEG 10-20 placement sites for the active electrodes, T3-T4 (for stabilization) was introduced first, followed by P4-T4 (for body relaxing) and FP2-T4 (emotional relaxation) when the optimal response frequency (ORF) was found, then FP1-T3 (for focus and attention) was introduced at double the ORF. Training began with 30 minutes at T3–T4 until ORF was determined, then each site was added sequentially over time after each site effect was determined. Left-sided training was added last only after the ORF was assured over time. When all four sites were included during a session, each site was trained for 8 minutes for a total of 32 minutes. Because of a brief assessment and discussion as well as set-up and follow-up instructions, each session was about one hour.

Prior to training, each head/scalp site was first cleansed with a distilled water-infused facial wipe to remove any sweat, grease, or grime. Nuprep, a skin prep gel, was utilized to further prep the skin, and a light smear of Ten20 conductive electrode paste was used at each site, before the electrodes with Ten20 paste were applied. Impedance was checked via the NeuroAmp (<http://www.beemedic.com/neuroamp.html>), which is utilized with the Cygnet System and has the convenient electronic capability to check for impedance at the time of electrode application. The direct measurement of contact impedance and offset voltage determined the adequate electrode contact quality at the beginning of a session and at each electrode change during the session. Before and after each session, all equipment and electrodes were cleaned in an aseptic manner following VA infection control protocols.

For each session of ILF NFB, the participant selected one of the feedback strategies incorporated in Cygnet NFB software packages: Dreamscapes, Dual Drive Extreme, Train Adventures, Inner Tube, Particle World, Roller Ball, Hyper Pong, or Tropical Heat. Each of these software packages offers a method for the participant to engage in training based on participant preference. Some of the packages offer adventure strategies (e.g., trains moving forward or planes flying to navigate different areas such as tunnels or mountains) or outdoor enjoyment (e.g., waterfalls, wilderness hike). All of the software packages are equal in capability to inform participants of their physiological brain wave patterning and responses.

Because the ORF for each participant is uniquely individualized and can range anywhere from .1 to as low as .0001, finding the ORF for each participant involves a lot of skill on the part of the NFB specialist. Specialized training (EEGInfo.com) in the Othmer method is necessary to begin to safely and effectively provide this type of NFB to participants. The ORF is determined in each participant via an intensive iterative procedure based on the response of the participant to the feedback signal during the initial training sessions. Moving too fast, too slow, not far enough down the frequency range, or too far down the frequency range can cause some physical and emotional discomfort for the participant, which is reversible if the NFB specialist is skilled in the process.

The intervention included 20 NFB training sessions three times weekly for each participant by a trained and board-certified (Biofeedback Certification International Alliance) NFB specialist. A specific five-symptom checklist (see Table 1) was used to direct each training session. This specific checklist is comprised of the five symptoms most likely to be important to the participant, and was updated at each session with the participant's current status on these symptoms. The NFB specialist carefully documented all settings used and responses to treatment. Session training forms, which recorded all settings and electrode placements and the results obtained, were used at each session to ensure treatment consistency and to determine participant goal attainment. Study participants were seated in a comfortable chair throughout the treatment session. The participants received instruction to simply observe the game strategy. Assessments were made at baseline, midtreatment, and at the completion of the 20 NFB sessions.

### Assessments

Twelve assessment tools were utilized in this pilot study. They included the Headache Impact Test (HIT-6; Kosinski et al., 2003); TBI-Quality of Life (QOL) Headache Pain

Short form (TBI-QOL Headache; Tulskey et al., 2019); Insomnia Severity Index (ISI; Bastien, Vallieres, & Morin, 2001); Sleep Disturbance short form (NEUROQOLTBI Sleep; Cella et al., 2012); QIKtest Continuous Performance Test (QIKtest; Othmer, 2014); Quality of Life After Brain Injury (QOLIBRI; Truelle et al., 2010); Satisfaction with social roles and activities short form (NEUROQOLTBI Satisfaction; Cella et al., 2012); Ability to participate in social roles and activities short form (NEUROQOLTBI Ability; Cella et al., 2012); General Symptom Inventory (GSI, Carlson, 1980-2021); Depression, Anxiety and Stress Scale-21 (DASS-21; Lovibond & Lovibond 1996); Patient Health Questionnaire-9 (PHQ-9; Kroenke & Spitzer, 2002); and Posttraumatic Stress Disorder Checklist (PCL-5; Weathers et al., 2013).

### Statistical Analyses

Participant demographics were presented using frequencies and percentages for categorical variables and means for continuous variables. For each hypothesis, mean score for each assessment tool was determined and the difference in mean score from baseline to posttreatment was identified. Established clinically significant shift indicators were compared to determine clinical significance, or scores were compared with established clinically significant shift indicators to determine clinical significance.

### Results

The study team had 1 year to conduct the study, including obtaining the necessary equipment, training, and approvals. Dr. Judy Carlson, the Principal Investigator, was then limited to only 3 months to complete the intervention. Although 19 veterans expressed interest in participating in the pilot study, challenges in travel arrangements, cost, or scheduling prevented all but four from participating.

Four veterans with a deployment-related mTBI who were experiencing headaches, insomnia, and attention difficulties consented and received the full course of NFB treatment. The veterans were male, 35–56 years old (mean age 42), experienced 2–5 concussions while in theater, were considered by the VA to be 50%–100% disabled, and had experienced 5–10 years of PCSs. All four received the intervention and completed the 20 sessions of NFB. There were no dropouts.

Assessment results depicted a 9- to 48-point change from the baseline to the posttreatment assessments. The results on each of the assessment tools and the clinically significant treatment shift indicators can be found in Table 2.

**Table 1. Symptom checklist**

ID#	Issue	Assessment										
		No Issue					Worst issue					
1	Headache	0	1	2	3	4	5	6	7	8	9	10
2	Sleep Issue (onset & maintenance)	0	1	2	3	4	5	6	7	8	9	10
3	Attention Issue (Focusing)	0	1	2	3	4	5	6	7	8	9	10
4	Lack of Energy	0	1	2	3	4	5	6	7	8	9	10
5	No motivation	0	1	2	3	4	5	6	7	8	9	10

Top five issues for NFB training assessment. Note: All participants will have Headache, Sleep issue (will identify what the issue is), and Attention issue (will identify what the issue is) on assessment form since these are related to study focus. Participants can identify two other areas on which they wish to focus and have improvement. The first assessment is how they have been generally been experiencing these 5 symptoms over the past month. Thereafter, the following assessments on these 5 symptoms will be based on their experience of these issues since their last NFB intervention session. Based on assessment, the NFB Specialist will determine how to adjust frequency. For instance, if assessment scores are better, but not a 0 or 1, the NFB specialist will continue to adjust frequency slowly and an iterative manner until the optimal response frequency (ORF) is identified. The expectation is that the participant will achieve a lower score on each of the issues. It was not unusual for participants with high scores in the beginning of treatment, to achieve a score of 0, 1, 2 or 3 by the end of treatment on all issues.

**Discussion**

The primary objective of this pilot study was to demonstrate that conducting a full clinical trial was feasible at a VA located in the Pacific region. The secondary objective was to assess the impact of NFB on chronic headaches, insomnia, attention difficulties, quality of life, and emotions among VA veterans with mTBI.

Four participants completed the protocol, although 15 more were interested. All necessary equipment and approvals were obtained, and all procedures were fully conducted. This supports the feasibility of a clinical trial using NFB for VA veterans with mTBI.

The cost of travel (gas and time), inconvenience of finding parking, and time frame of the pilot study were the reasons veterans gave for why they did not want to participate in the pilot project. Table 2 outlines the strategies that will be used with grant funding to address these issues in the conduct of a 4-year clinical trial.

The four participants demonstrated significant clinical gains from pre- to postintervention in each of the areas assessed—headache, sleep, attention, and quality of life—as well as on scales that measured PTSD, depression, distress, and general symptoms. During or at the conclusion of the study, the participants did not communicate any adverse reactions. In fact, they often commented on the opposite: for example, “I finally can think more clearly. I haven’t been able to do that for years”; “My headaches are gone, I never believed that could ever happen”; “I am falling asleep

at night, just like that. I don’t have to have a few drinks to fall asleep anymore”; and “I have not had to use any headache medications [during the course of NFB treatment].”

There were several limitations of this pilot project, the first being the time constraint in which to begin and complete the study. Other limitations included the lack of a control group and the small sample size. However, even with the brief marketing of the study, over a dozen more veterans indicated their interest, but due to the time constraints related to the study and lack of funding they did not participate.

**Conclusion**

Because all the procedures related to a randomized, controlled trial were successfully conducted, the pilot study demonstrated feasibility. All issues encountered in this pilot study were related to time constraints of the project and the need for funding. The data obtained from the four veterans were very positive. All hypotheses were supported as demonstrated by the significant clinical gains reported on the 12 questionnaires despite the small sample size. As has been clearly indicated in the literature, the experience of chronic headaches, insomnia, and attention difficulties can lead to debilitation in all areas of veterans’ lives. The implementation of a randomized, controlled clinical trial can provide support for the use of ILF NFB with veterans to alleviate their chronic symptoms and enhance their quality

**Table 2. Summary of pilot outcome data (N = 4)**

Questionnaire	Baseline Score M	Posttreatment Score M	Mean Score Change from Baseline to Posttreatment	Clinically Significant Change
HIT-6 <sup>a</sup>	63.75	43.50	20.25	2.3 points
TBI-QOL Headache Pain <sup>a,b</sup>	59.93	50.38	9.55	7 points
NEUROQOLTBI Sleep <sup>a,b</sup>	66.48	48.23	18.25	7 points
ISI <sup>a</sup>	22.75	3.25	19.50	3 points
QIK Test <sup>a</sup>	13.00	0.75	12.25	30%
NEUROQOLTBI Satisfaction <sup>b,c</sup>	38.63	50.45	-11.82	7 points
NEUROQOLTBI Ability <sup>b,c</sup>	40.48	52.35	-11.87	7 points
QOLIBRI <sup>c</sup>	50.38	88.43	-38.04	30%
PCL-5 <sup>a</sup>	54.00	10.75	43.25	10 points
PHQ-9 <sup>a</sup>	15.00	2.25	12.75	5 points
DASS-21 <sup>a</sup>	61.00	15.00	46.00	12.7 points
GSI <sup>a</sup>	69.50	38.00	31.50	Less

*Note.* All mean change scores supported the hypotheses. Standard deviations are not provided due to the small number of participants. HIT-6 = Headache Impact Test; TBI-QOL = Traumatic Brain Injury-Quality of Life; NEUROQOLTBI = short forms from the Neurology Quality-of-Life measurement initiative; ISI = Insomnia Severity Index; QIK Test = QIKtest Continuous Performance Test; QOLIBRI = Quality of Life after Brain Injury questionnaire; PCL-5 = Posttraumatic Stress Disorder Checklist; PHQ-9 = Patient Health Questionnaire-9; DASS-21 = Depression, Anxiety and Stress Scale-21; GSI = General Symptom Inventory.<sup>a</sup> Lower scores indicate symptom reduction. <sup>b</sup>Represents a T-score. <sup>c</sup>Higher scores indicate greater satisfaction.

of life as well as offer an efficacious and noninvasive treatment option. NFB is a viable, patient-focused intervention that offers veterans the opportunity for self-health management.

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## Disclaimer

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