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Effectiveness of Infra-Low Frequency Neurofeedback on Postconcussion Symptoms in Combat Veterans: Results of a Delayed Intervention Analysis

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Abstract

Introduction. The purpose of this study was to ascertain the impact infra-low frequency neurofeedback (ILF NFB) had on a group of combat veterans with postconcussive symptoms who served as a control group in a randomized controlled trial (RCT) and later completed a delayed intervention procedure. **Methods.** After completing the control procedures (eight weekly 15-min health-related discussions and four assessment sessions), veterans were invited to join a delayed intervention (twenty 30-min sessions of ILF NFB and three assessment sessions) group. Of 38 control group members, 32 went on to complete the delayed intervention procedures (16% attrition). **Results.** Comparing baseline to end of treatment measures, findings were clinically and statistically significant for headache ($p < .0001$), sleep ($p < .0001$) and attention ($p < .0044$). Additional measures of interest were also significantly improved following ILF NFB, including quality of life ($p < .0001$), depressive symptoms ($p < .0001$), and symptoms of posttraumatic stress disorder ($p = .0001$). Significant results remained at the 2-month follow-up on all measures, despite a history of chronicity for many years and prior treatment failure. **Conclusion.** ILF NFB holds promise to be a safe and effective intervention for those who suffer with postconcussive symptoms of chronic headache, sleep, and attention disorders.

Keywords: infra-low frequency neurofeedback; mTBI; postconcussive symptoms; veterans; sleep; headache; endogenous neuromodulation

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Introduction

Traumatic brain injury (TBI) is a common malady in the United States with over 4 million citizens experiencing a TBI annually, of which 90% are considered mild TBI (mTBI; Berman et al., 2023). About 40% of those with mTBI suffer from chronic symptoms (Voormolen et al., 2018) and often experience significant economic and functional impact affecting the ability to fully participate in their roles (e.g., work, family; Gaudette et al., 2022; Sharma, 2022). A special subset of those with mTBI are service members who were part of recent post-9/11 military operations. It has been estimated that over a 20-year period from 2001 to 2021, about 90% of 441,639 veterans diagnosed with TBI had an mTBI (Whiteneck et al., 2024). However, rather than blunt head injuries (e.g., from motor vehicle accidents or athletics) that usually cause mTBIs in civilians, the most common cause of TBI by combat veterans was exposure to explosive blasts from devices such as improvised explosive devices,

rocket-propelled grenades, and landmines. The whole-body exposure to the pressurization shock waves of the blasts causes very complex injuries in the brain, involving both focal injuries (direct impact of the brain's surface on the bony protuberances of the skull and body pressure pushing up into the skull cavity) and diffuse injuries (stretching and twisting of axons and blood vessels by shearing forces; Chapman & Diaz-Arrastia, 2014). In addition, there are frequently secondary, longer-duration brain injuries related to the activation of molecular and biochemical responses that were once thought to be self-limiting (i.e., lasting hours or days postinjury). These complex brain injuries often result in abnormal brain signaling, including impairments to normal brain connectivity and electrical brain waves and patterns, as well as disruptions of intra- and interhemispheric communication and inflammatory processes that last much longer, leading to chronic and debilitating symptoms (Chapman & Diaz-Arrastia, 2014; Hayes et al., 2016). These types of heterogenous and chronic symptom profiles have been identified in veterans diagnosed with mTBI due to blast exposure (Rowland et al., 2024). A recent review of the literature further validates the consistent and compelling evidence of the long-term effects of blast-related TBI in terms of poorer psychological health, greater healthcare utilization and disability levels, impacts on brain structure and function, and greater headache impact on daily life (Miller et al., 2024).

Data from the Military Health System Data Repository indicated that the frequent comorbidities with mTBI were headache, cognitive deficits, sleep-related problems, anxiety disorders, and posttraumatic stress disorder (PTSD; Agimi et al., 2024). When these symptoms persist, they can negatively impact veterans' self-rated health occupational status (ability to return to work, school) social functioning and quality of life (QOL; MacGregor et al., 2013; Morissette et al., 2011; Sakamoto et al., 2021; Schiehser et al., 2015). Because of the complexity of the brain injury and prevalence of comorbid complications, combat-related mTBIs can prove difficult to treat. Therefore, developing and implementing effective strategies to reduce the persistent symptoms associated with mTBI is of critical importance.

According to the 2021 VA/DoD clinical practice guidelines for the management and rehabilitation of postacute mTBI (Eapen et al., 2022), the current treatment for postconcussive symptoms (PCS) remains symptom focused. Veterans with migraine headaches associated with mTBI are often treated with abortive agents (e.g., Triptans) and preventive medications (e.g., anticonvulsants and tricyclics; Theeler & Erickson, 2012). Cognitive dysfunction and insomnia are treated with cognitive rehabilitation programs, cognitive behavior therapy, occupational therapy, and medications (Ayalon et al., 2007). Symptom management results in addressing one concern at a time with treatments that may be temporary, not fully tackling the concern, or may even result in additional side effects and complications. While cognitive rehabilitation and psychological support are widely used to treat mTBI PCS, neither has been shown to be effective in addressing the core brain deficits associated with mTBI (Duff, 2004). Since symptoms often return and persist, it is clear that improved treatment options for these persistent PCS need to be developed for veterans with mTBI (Morissette et al., 2011).

A more targeted approach to the treatment of TBI would be to enhance latent neuroplasticity which may establish a more normalized or stable brain (DeFina et al., 2009). The ability to recruit neuroplastic mechanisms in the service of rehabilitation has been demonstrated by neurofeedback (NFB), as reflected in microstructural changes in white and gray matter (Enriquez-Geppert et al., 2013; Ghaziri et al., 2013; Ros et al., 2013). NFB has been shown to contribute to functional rehabilitation by restoring network connectivities in areas of the brain that may have been impaired, rehabilitative changes that appear to be sustained over the longer term (Ibric et al., 2009). Functional magnetic resonance imaging (fMRI) studies further validate that NFB may be useful in promoting recovery from neurological disorders rooted in abnormal patterns of brain connectivity (Haller et al., 2013; Koush et al., 2013). Hence, NFB, a noninvasive and nonpharmacological modality, may be used to improve functionality by remediating abnormal network relationships, including both steady-state and dynamic connectivity (Haller et al., 2013).

ILF NFB, a novel type of NFB, was initially conceived in 2006 and has developed over time to its present level of clinical maturity (Othmer & Othmer, 2020; Othmer, 2023). ILF NFB primarily utilizes the slow cortical potential domain, which refers to brainwave frequencies below 0.1 Hz (Othmer & Othmer, 2020). It requires a very specialized type of instrumentation that can isolate and provide information back to the brain about its functioning in the infra-low frequency regime. The Cygnet NFB instrument (https://www.beemedic.com/cygnet.html), an example of equipment that has the

ILF capability to access brainwave frequencies as low as .000001 (Othmer, 2023) was used in this study. Since ILF NFB differs from conventional NFB with respect to focus, mechanisms of action, and the role of both therapist and client, this innovative type of NFB is still new to most neuroscience and NFB experts and practitioners, most of whom still work with methods grounded in traditional operant conditioning.

Unlike traditional NFB, ILF NFB recruits 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). The use of bipolar montage reveals the dynamics of selected critical linkages within the intrinsic connectivity networks, and on that basis the brain adjusts its activity level, moderates neuronal excitability, and alters connectivity relationships. Since the brain is reacting to, and acting upon, slowly varying intrinsic network activity, this process is most appropriately referred to as endogenous neuromodulation. This is the essential distinction that sets ILF NFB apart from conventional NFB, which involves explicit targeting in what is typically an operant conditioning design. ILF NFB fundamental mechanism of action is the renormalization of the steady-state and dynamic functional connectivity of the resting state networks. Since the low frequencies establish the context for the activation and interaction of neuronal assemblies, they present a potent and most efficient target for functional renormalization (Buzsáki & Watson, 2012; Monto et al., 2008).

NFB has been used since the 1960s for symptoms related to mTBI. Duff (2004), in his extensive review of the literature, suggests that since the 1960s, studies using NFB (EEG biofeedback or neurotherapy) have shown that patients can be taught to recover normal functioning in brains with excessively slow wave activity, which is often observed in PCS. In a 2013 review of the literature, May et al. used a 10-level classification rubric to classify the research literature of NFB and mTBI, with 10 being the highest level (e.g., randomized controlled trials [RCT]) and 1 being the lowest (e.g., case study/anecdotal evidence). They found two studies at level 5 (randomized waitlist or intention to treat), six studies at level 3 (historical control), ten studies at level 2 (no control group) and five studies at level 1 (case study/anecdotal evidence). Of the 23 studies reviewed, all found NFB to positively impact symptoms associated with mTBI (attention, memory, quality of life, sleep, motor control, coordination, depression, headaches). May et al. (2013) called for more RCT to further support the efficacy of NFB treatments. Recent studies have continued to demonstrate support for the use of NFB with symptoms related to mTBI. Nelson and Esty (2012) found in their small study (n = 7) that neurotherapy significantly reduced depression, somatic and memory/attention symptoms, when employed with Operation Enduring Freedom and Operation Iraqi Freedom veterans diagnosed with TBI and PTSD. A study conducted in 2013 demonstrated that NFB was able to enhance quality of life and perceived control in 29 service members with mTBI and PTSD (Strang & Chae, 2013). In a control group/waitlist study conducted in 2014, sixty mTBI participants (aged 18–49 years old) received NFB, and it was found that 20 sessions of NFB significantly improved quality of life (Reddy et al., 2014). Munivenkatappa et al. in 2014 provided further validation of the ability of NFB to enhance structural and functional connectivity and cognitive scores of mTBI patients. Arns and Kenemans in 2014 reported in their review of the literature regarding attentional and sleep disorders that NFB is associated with improved sleep quality and sleep onset. After a thorough meta-analysis of NFB research, Larsen and Sherlin rated NFB "probably" efficacious for the treatment of mTBI symptoms (2013).

Since ILF NFB is a more recently developed technology, to date there have been few published studies that have demonstrated the efficacy of ILF NFB relating to veterans with mTBI who experience chronic PCS including headache, insomnia, and attention dysfunction. Previous research suggested that ILF NFB positively affected change in postconcussive symptom severity (Carlson & Ross, 2021; Legarda et al., 2022). Other studies found that ILF NFB decreased incidence of both migraines and tension-type headaches (Arina et al., 2022; Dobrushina et al., 2017). However, these studies' findings have limited generalizability due to methodological limitations such as selection bias (Legarda et al., 2022) and small sample size (Arina et al., 2022; Carlson & Ross, 2021; Dobrushina et al., 2017). Though not in a population with mTBI, ILF NFB has also demonstrated clinical efficacy in addressing symptoms of depression (Grin-Yatsenko et al., 2018). There are also several publications on the efficacy of ILF NFB in clinical settings (Benson & LaDou, 2015; Kirk & Dahl, 2022; Legarda et al., 2011; McMahon, 2020; Othmer & Othmer, 2009; Shapero & Prager, 2020).

This paper presents additional analysis of data from veterans who completed all control group

procedures as well as all delayed intervention procedures during a 5-year RCT. The RCT was conducted with veterans who experienced an mTBI while participating in post-9/11 military operations to evaluate the impact of ILF NFB on chronic PCS of headache, insomnia, and attention dysfunction. Initial results of this trial that included all randomized participants using an intention-to-treat analysis demonstrated significant differences between the intervention and control groups with strong effect sizes at end of treatment on all outcome measures (Carlson et al., 2025). Because of the known probable effectiveness of ILF NFB for veterans with mTBI by the research team from previous pilot study and clinical practice experience, the team felt an ethical compulsion to design the study to include a delayed intervention arm of the study. For this analysis, it was hypothesized that ILF NFB would improve veterans' headache, sleep, and attentional symptoms above and beyond those results received while serving in the control group.

Methods

The initial RCT study was a parallel RCT, which used block randomization set of four (2 treatment, 2 control) to ensure that each group had a similar number of participants. The biostatistician created the blocks and placed group assignments in individual security envelopes. Once the control group completed all control group procedures, they were invited to enter the delayed intervention group.

Research Ethics

This study was performed in line with the principles of the Declaration of Helsinki. All procedures of this study were performed in compliance with relevant laws and institutional guidelines and was approved by the Veterans Administration Pacific Islands Health Care System Institutional Review Board Approval Number: 2019-06-JC/Promise 0003.

Inclusion and Exclusion Criteria

Participants included veterans who had received a diagnosis of mTBI associated with post-9/11 military operations, were between the ages of 18 and 65, and experienced the PCS symptoms of interest (chronic headaches, insomnia, and attention difficulties). To be eligible, participants also needed to be able to read and write English, comprehend what was read, and follow directions. The diagnosis of mTBI was verified for each veteran via electronic health records. Veterans were excluded if they were under the age of 18 or over the age of 65; were pregnant at the time of the study; had a severe TBI diagnosis or impaired decision-making capacity; were unable to comply with study visit schedule; or endorsed active suicidal intent on the Columbia Suicide Severity Rating Scale (Posner et al., 2011).

To recruit veterans, letters about the study with its contact information were sent to eligible veterans that were identified by a clinical informatics data pull after a waiver of Health Insurance Portability and Accountability Act was obtained. Two weeks after the letter was sent, a member of the research team telephoned the veteran to answer any questions. Also, veterans could be referred to the study by providers, or veterans could self-refer based flyers and other marketing materials advertising the study. Veterans who completed the control group procedures were invited to enter the delayed intervention arm.

Setting and Location

The study was conducted from 2020 to 2025 at a midsized outpatient Veterans Health Administration facility located in Oahu, Hawaii. Four private research spaces in compliance with human research standards (e.g., privacy, safety), were utilized for the consenting, treatments, and assessment sessions.

Consenting and Randomization Procedure

The privacy rights of potential participants were observed, and all interested veterans who met the eligibility criteria underwent an informed consent procedure which included information about the opportunity for veterans in the control group to enter a delayed intervention group once all control group procedures were completed. All those consented were administered the Columbia Suicide Severity Rating Scale (Posner et al., 2011). Anyone who screened positive for suicidality was redirected to same-day mental health services available in the clinic. Those veterans who did not screen positive for active suicide intent were randomized into the intervention or control group by the research coordinator who used the block of four security envelopes until the four were distributed, then the next block of four would be used. Once randomized, the participant was considered enrolled in the study and scheduled for the baseline assessment.

Primary Outcome Measures

For the RCT, the outcome assessment measures were administered to the intervention and control groups at baseline, midpoint, end of treatment, and at a 2-month follow-up by the research assistant or research coordinator. Once the control group procedures were completed, the 2-month follow-up outcome assessment served as the baseline outcome assessment for the delayed intervention

group. Those in the delayed intervention group completed additional assessments after 10 sessions of ILF NFB, after completion of all 20 sessions, and 2 months after completion of ILF NFB treatment. All outcome assessments for the delayed intervention group were administered by the research assistant or research coordinator.

Headache Measures.

- Headache Impact Test (HIT-6; Kosinski et al., 2003) is a 6-item measure describing people's feelings and impact of their headache over the past month. The score range is 36–78, with lower scores indicating less headache impact. The clinically significant change score index is 2.3 points (Coeytaux et al., 2006).
- TBI-Quality of Life Headache Pain Short form (TBI-QOL Headache; Tulsky et al., 2019) is a 10-item instrument that measures headache pain over the past week. The raw score range is 10–50, with lower scores indicating less pain. The clinically significant change score index is 7 points (Portz et al., 2017).

Sleep Measures.

- Insomnia Severity Index (ISI; Bastien et al., 2001) is a 7-item measure, assessing the severity, perception, and consequences of the person's insomnia over the past 2 weeks. Insomnia scores are as follows: 8–14, subthreshold insomnia; 15–21, moderate severe insomnia; and 22–28, severe insomnia. The clinically significant change score index is 3 points (Yang et al., 2009).
- Sleep Disturbance short form (NEURO QOL Sleep; Cella et al., 2012) is an 8-item form that measures a person's reported sleep disturbance over the past 7 days. The raw score range is 8–40, with lower scores indicating less disturbance. The clinically significant change score index is 7 points (Kozlowski et al., 2016)

Attention Measure. QIKtest Continuous Performance Test (QIKtest; Versace, 2014) is a computerized visual continuous performance 21-min test. The Accuracy Index was used as the attention measure which reflects sustained attention and impulse control. Sustained attention is determined by omission errors and outliers in regard to response times, and impulse control is determined by commission errors and anticipatory errors. The Accuracy Index score range is 165–460 with a higher score suggesting better attention. The clinically significant change score index is 7 points.

Secondary Outcome Measures

QOL Measures.

- QOL After Brain Injury (QOLIBRI; Truelle et al., 2010) is a 37-item questionnaire that assesses life since the brain injury. The raw score range is 0–100, with higher scores suggesting greater satisfaction. The clinically significant change score index is a 30% shift.
- Satisfaction with social roles and activities - short form (NEUROQOLTBI Satisfaction; Cella et al., 2012) is an 8-item instrument that measures a person's satisfaction with social roles and activities over the past seven days. The raw score range is 8–40, with higher scores indicating greater satisfaction. The clinically significant change score index is 3.7 points (Portz et al., 2017).
- Ability to participate in social roles and activities short form (NEUROQOLTBI Ability; Cella et al., 2012) is an 8-item instrument that measures a person's perception of their capability to participate in social roles and activities in the past seven days. The raw score range is 8–40, with higher scores suggesting an increased ability. The clinically significant change score index is 3.9 (Portz et al., 2017).

Variables of Interest.

- Depression, Anxiety and Stress Scale–21 (DASS-21; Lovibond & Lovibond, 1995) is a 21-item instrument that assesses depressive, anxious, and stress symptoms over the past week. Total score range is 0–63, with the following interpretive ranges: 17-20, mild distress; 21–25, moderate distress; 26–29, severe distress; and 30+, extremely severe distress. The clinically significant change score index is 12.7 points (Ronk et al., 2013).
- Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001) is a 9-item instrument that assesses depression. The score range is 0–27, with a score of 10 suggesting moderate depression and lower scores suggesting fewer depressive symptoms. The clinically significant change score index is 5 points (Kroenke, 2012).
- PTSD Checklist (PCL-5; Weathers et al., 2013) is a 20-item instrument that assesses the symptoms of PTSD in the past month. The score range is 0–80, with a score of 31–

33 suggesting probable PTSD, and lower scores indicating less PTSD symptoms. The clinically significant change score index is 10 points (Weathers et al., 2013).

- General Symptom Inventory (GSI; Carlson, 2021) is a 117-item instrument that assesses general health symptoms over the past month. Each item is a 5-point scale with 0 = *did not apply to me at all* to 4 = *applied to me very much, or most of the time*. Total score range is 0–464, with lower scores suggesting less severity or less frequency of the item. The clinically significant change score index is a 30% change.

Sample Size. For the RCT, it was determined that 72 participants (36 in each group, intervention and control) were needed to attain the goals of the study. Up to 100 veterans were projected to be recruited to achieve the 72 enrolled participants to complete the study. Literature on NFB studies of patients with TBI have reported dropout rates ranging from 10% to 30% (Nelson & Esty, 2012; Zoefel et al., 2011). Assuming a dropout rate of 28% and a moderate autocorrelation of 0.6 among repeated measures, this sample size ensured the detection of an average difference of at least 0.49 standard deviations with a power of 80% in the NFB intervention group compared to the control group using a two-tailed significance level of 0.05. For the delayed intervention analyses, the sample size consisted of those control group completers (n = 38), who were willing and able to enter the delayed intervention group.

Procedures

The procedures for control group whose members then became the delayed intervention group are as follows:

Control Group. Control group participants received eight phone calls (one call/week) over the course of 8–10 weeks. Calls were completed by one of the four clinical investigators. Each call was approximately 15 min, and one health topic was discussed. The health topics discussed included sleep hygiene, basic nutritional concepts, beverage choices, positive thinking, thought reframing, fitness, daily calming activity, and enhancement of focus strategies. A script for each of these topics was used to guide each call.

Delayed Intervention Group. The delayed intervention group participants completed 20 half-hour ILF NFB sessions, typically receiving three sessions per week over an 8- to 10-week period. ILF NFB treatments were provided by one of four licensed healthcare employees, who had received substantial ILF NFB training. The principal investigator was one of the four ILF NFB providers with extensive experience in NFB as well as Board Certification in Neurofeedback by the Biofeedback Certification International Alliance. The other three ILF NFB providers received formal and ongoing optimal response frequency (ORF) precision training and supervision from the principal investigator. Reliability between the four ILF NFB providers was established using a procedure developed by the principal investigator to determine the level of fidelity of providers' decisions in response to clinical data from a case study presented. This procedure yielded an inter-rater skill-level reliability of .95 among the providers. A coaching script was used by the ILF NFB providers during the ILF NFB sessions to keep the interactions approach consistent with all the participants.

All procedures were explained in advance to participants and voluntary participation affirmed. At the first session, participants also filled out a clinical symptom checklist of five symptoms (Carlson & Ross, 2021). The first three symptoms were specific to the study aims (headache, sleep, and attention), while the additional two items were specific to each participant's self-identified symptoms of interest and selected at their initial assessment session. Participants rated these five items on an 11-point Likert scale (0–10, where 0 was *No Issue* and 10 was *Worst Issue*); the initial ratings were reflective of their experience over the past month, while in each subsequent session, participants indicated their experience of those symptoms that day. ILF NFB providers were never privy to participants' assessment outcome measures data during the course of the study, so these recurring clinical symptom ratings, as well as other feedback provided by participants on their experience within and between sessions, were the clinical data that ILF NFB providers used to make decisions about the treatment protocol.

The precision model of ILF NFB, based on the Othmer ORF protocol (Othmer & Othmer, 2020), was further refined by the principal investigator and utilized for the participants in this study. The ORF protocol establishes through an iterative process the specific frequency point within the ILF spectrum that is optimal for resolution of the symptoms being experienced in real time during the session (e.g., tension or pain in shoulders, racing thoughts). The iterative process includes the prompting of participants every 2–3 min to describe their

subjective experience of the specific symptoms identified and, based on these descriptions, the ILF NFB provider carefully interprets its meaning and methodically adjusts the frequency (higher or lower) until the unique ORF is identified for each participant. Typically, a participant's ORF was identified within the first 4–6 sessions; symptom tracking over the course of treatment further verified that the participant's ORF had been identified. More information about the ILF NFB procedures followed is outlined in the report of the pilot study (Carlson & Ross, 2021).

Participants completed 30 min of ILF NFB at each session, during which they were instructed to look at the computer monitor; the moving images on the screen provided prompt feedback to participants about their brain functioning as ascertained by electrodes placed on the scalp (Huster et al., 2013). Working with bipolar montage, the brain gets feedback (neuroceptively) on the dynamic differential activation at the two sites. This information is sufficient for the brain to regulate its state of activation by way of a whole-brain response that over time allows for resolution of subjective symptoms and enhanced functioning. Electrode placement followed the 10–20 international system of electrode placement (Hughes, 1994). Per study protocol, sites used were right parietal (T4–P4), interhemispheric (T3–T4), right frontal (T4–Fp2), and left frontal (T3–Fp1), though the combination of sites was individualized to the participant based on their response to the intervention. The unique ORFs for all participants in this study were identified and ranged from .000004 to .973096 Hz, with a median frequency of .002825 Hz.

Statistical Analysis

The initial between-subjects' results of the RCT are reported in Carlson et al. (2025). The present analysis represented an additional objective of the RCT, which was to evaluate the effectiveness of ILF NFB for participants who were initially randomized into the control condition and later received ILF NFB as a delayed intervention.

This analysis assessed outcome scores at the endpoint and 2-month follow-up assessments, comparing participants following ILF NFB treatment to their own assessment scores from their control group participation**.** The control group's 2-month follow-up assessment served as the baseline for the delayed intervention analyses. A paired-sample *t*-test was used to evaluate the mean difference in outcome scores between treatments, at 5% type-I error rate. Additionally, mean scores were estimated at multiple time points, including midtreatment, with corresponding 95% confidence intervals (CIs). The analysis followed a per-protocol approach, including only participants who completed the treatment phases and the required assessments. It is important to note that the reported 95% CIs serve as guidelines only, as no adjustments were made for multiple comparisons across time points. All statistical analyses were performed using SAS software, version 9.4M8.

Results

Participants

Of the 44 randomly assigned to the control group, 38 participants completed the control group procedures per protocol, with 32 participants completing the delayed intervention per protocol, an attrition rate of 16%. No adverse event was related to the treatment; most were related to other illnesses (e.g., COVID-19) that forced rescheduling appointments, and no participant withdrew because of the intervention. Figure 1 demonstrates the complete details of participant flow through this study.

The average age of participants was 45 years (*SD* = 8.7). The majority were male (89.5%), and the two most frequently reported ethnic group identified were biracial/multiracial (31.6%) and White (23.7%). Table 1 includes additional details on participant demographics, as well as baseline scores on the variables of interest for the present analyses.

Primary Variables of Interest Analyses

The study's main hypothesis was that participants would demonstrate significant improvement in symptoms related to headaches, sleep disturbance, and difficulty with attention following completion of the delayed intervention when compared to their initial assessments on these variables during participation in treatment-as-usual control conditions. Paired-sample *t*-tests supported this hypothesis. A paired *t*-test demonstrated that veterans reported improved headache symptoms after completing NFB treatment at both the endpoint assessment, $p < .0001$, $d = 1.28$; and after a 2-month delay, $p < .0001$, $d = 1.01$. This pattern was also true for the TBI QOL Headache Pain measure at the conclusion of treatment, $p = .0001$, $d = 1.12$; and at the follow-up assessment, $p < .0001$, $d = 0.94$. Paired *t*-tests also demonstrated significantly improved subjective report of sleep following NFB treatment at the endpoint assessment, $p < .0001$, $d = 1.34$; and at the 2-month follow-up assessment $p < .0001$, $d = 0.98$. This

Figure 1. *CONSORT Delayed Intervention Participant Flow Diagram.*

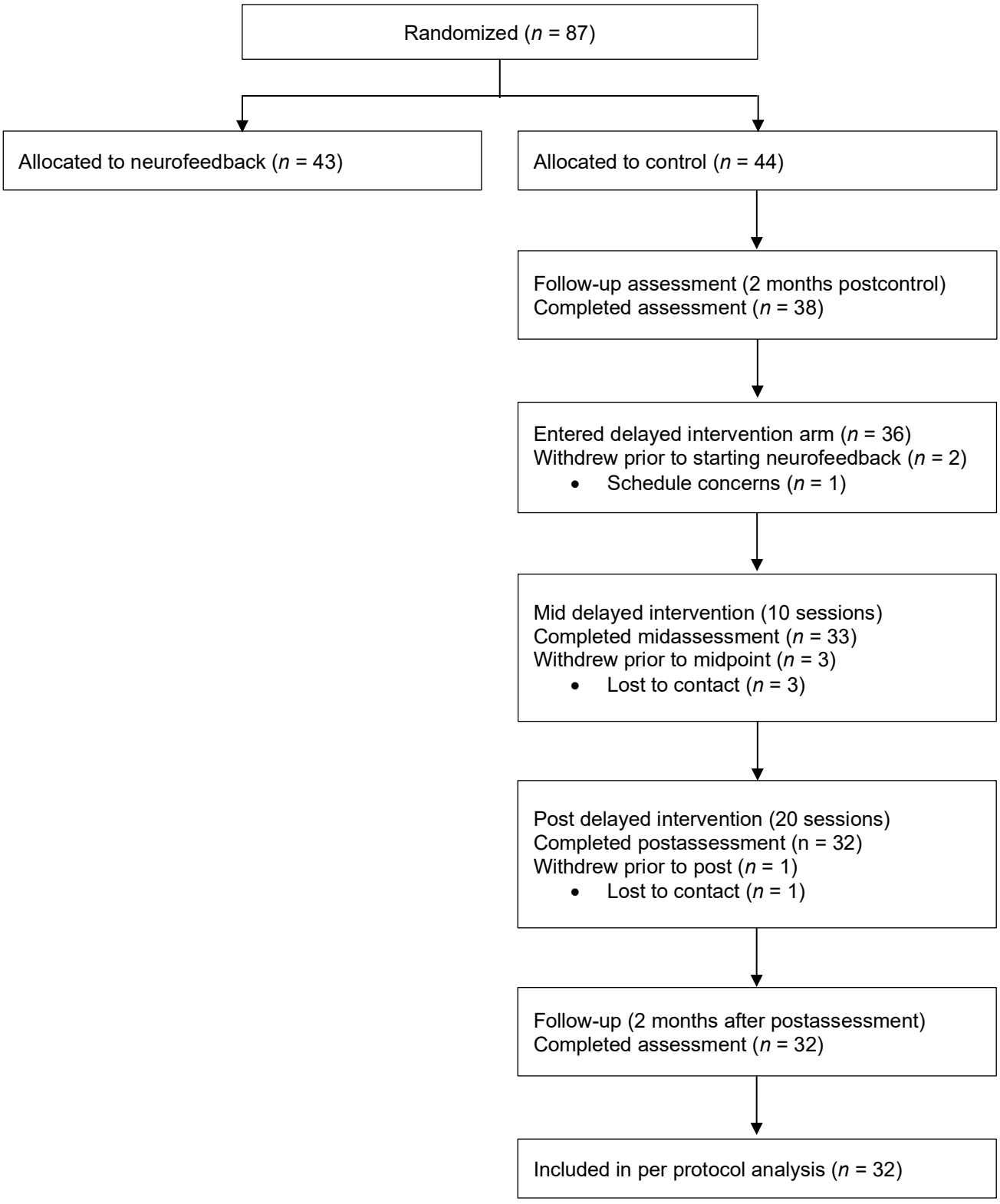

Table 1

Baseline Participant Characteristics and Test Scores

	Control Group Completers (*N* = 38)
Participant Demographics	
Age	45.5 (8.7)
Gender (Male)	34 (89.5%)
Self-identified Ethnicity	
African/Black	7 (18.4%)
European/White	9 (23.7%)
Asian	5 (13.2%)
Native American	0 (0%)
Hispanic	2 (5.3%)
Hawaiian/Pacific Islander	1 (2.6%)
Biracial/Multiracial	12 (31.6%)
Refused/Unknown	2 (5.3%)
Delayed Intervention Completers Primary Variables of Interest at Baseline (*n* = 32)	
HIT-6	62.6 (5.6)
TBI QOL Headache Pain	32.2 (8.5)
ISI	16.9 (5.6)
Neuro QOL Sleep Disturbance	25.1 (6.0)
QIK-Test	259.3 (44.9)
Delayed Intervention Completers Secondary Variables of Interest at Baseline (*n* = 32)	
QOLIBRI	46.3 (17.2)
Neuro QOL Participate	24.4 (5.7)
Neuro QOL Satisfaction	21.9 (6.1)
PCL-5	36.5 (18.7)
PHQ-9	13.0 (5.7)
DASS-21	22.9 (12.4)
GSI	149.7 (19.0)

Note. Participant features observed at baseline are summarized as counts with percentages of the total indicated in parentheses, with the exception of age. Participant age and test scores observed at baseline are summarized as average with standard deviation indicated in parentheses.

pattern also held true for the Neuro QOL Sleep Disturbance subtest, which demonstrated improvement in scores following NFB treatment compared to the control group procedure at endpoint, $p < .0001$, $d = 1.43$; and at the 2-month assessment, $p < .0001$, $d = 1.10$. Finally, a paired *t*-test showed significant improvement in attention at completion of the NFB treatment compared to completion of the control group protocol, $p = .0197$, $d = 0.43$; and at the 2-month follow-up assessment, $p = .0497$, $d = 0.32$. See Table 2 for additional details of these analyses.

Table 2
*Result**

Measure	Delayed Intervention Baseline	Assessment Point	Post Delayed Intervention	*p*-value	Cohen's *d***
Primary Variables of Interest					
HIT6	62.6 (60.2, 65.1)	End	51.8 (48.3, 55.2)	<.0001	1.28
		Follow-up	54.0 (50.5, 57.5)	<.0001	1.01
TBI QOL Headache Pain	32.2 (28.8, 35.5)	End	21.2 (17.8, 24.6)	<.0001	1.12
		Follow-up	22.7 (19.1, 26.3)	<.0001	0.94
ISI	16.9 (15.0, 18.8)	End	8.6 (6.2, 11.0)	<.0001	1.34
		Follow-up	10.7 (8.2, 13.2)	<.0001	0.98
Neuro QOL Sleep Disturbance	25.1 (23.3, 26.9)	End	16.9 (14.8, 19.1)	<.0001	1.43
		Follow-up	18.6 (16.2, 20.9)	<.0001	1.10
QIK-Test	259.3 (241.2, 277.4)	End	281.4 (263.1, 299.6)	.0197	0.43
		Follow-up	276.4 (255.8, 297.0)	.0497	0.32
Secondary Variables of Interest					
QOLIBRI	50.8 (45.4, 56.2)	End	66.9 (59.9, 73.9)	<.0001	0.91
		Follow-up	64.0 (55.6, 72.3)	<.0001	0.67
Neuro QOL Participate	25.2 (23.4, 27.0)	End	29.0 (26.7, 31.3)	<.0001	0.66
		Follow-up	29.0 (26.3, 31.7)	.0030	0.60
Neuro QOL Satisfaction	23.3 (21.3, 25.4)	End	28.2 (25.4, 31.0)	<.0001	0.70
		Follow-up	28.2 (25.4, 31.1)	.0013	0.70
PCL-5	36.5 (30.6, 42.4)	End	19.8 (13.3, 26.2)	<.0001	0.94
		Follow-up	20.2 (13.9, 26.4)	<.0001	0.93
PHQ-9	13.0 (11.1, 15.0)	End	6.1 (4.3, 8.0)	<.0001	1.23
		Follow-up	7.0 (4.7, 9.2)	<.0001	0.99
DASS-21	22.9 (19.0, 26.8)	End	10.3 (6.5, 14.2)	<.0001	1.10
		Follow-up	12.9 (8.5, 17.2)	<.0001	0.84
GSI	149.7 (130.5, 168.9)	End	82.0 (58.9, 105.1)	<.0001	1.11
		Follow-up	91.3 (66.9, 115.7)	<.0001	0.93

*Result Table displays mean outcome scores at three time points during the delayed intervention—baseline (i.e., follow-up of the control phase), end of treatment, and follow-up—with corresponding 95% confidence intervals. The reported *p*-values reflect within-group differences in mean scores at the end of the delayed intervention and at the 2-month follow-up compared with the delayed-intervention baseline. Analyses were conducted using a per-protocol approach. Within-group comparisons were performed using paired-sample *t*-tests, with corresponding *p*-values and Cohen's *d* effect sizes reported.
** Cohen's *d* effect size Legend: 0–0.2 = not relevant; 0.2–0.5 = Small Effect Size; 0.5–0.8 = Moderate Effect Size; 0.8–1.3 = Large Effect Size; 1.3+ = Very Large Effect Size

Secondary Variables of Interest Analyses

In addition to the study's main variables of interest, participants provided self-report data regarding quality of life, trauma-related symptoms, depressive symptoms, and generalized symptoms. The hypothesis again was that participants would demonstrate improvement on these secondary variables of interest following their participation on NFB treatment compared to their scores upon completion of the initial control group protocol. This hypothesis was supported for all variables, as results showed improvement above and beyond thatseen upon completion of the control group procedure on all variables. In regard to quality of life, participants had significantly improved scores on the QOLIBRI, with participants reporting higher scores upon completion of treatment compared to completion of the control condition both at the endpoint assessment, $p < .0001$, $d = 0.91$; and at the 2-month follow-up, $p = .0004$, $d = 0.67$. This was also true on the Neuro QOL Participate subtest upon completing NFB treatment at the end of the study, $p < .0001$, $d = 0.66$; and at the 2-month follow-up, $p = .003$, $d = 0.60$. A similar pattern was found for the Neuro QOL Satisfaction subtest, with participants demonstrating higher scores upon completion of the treatment condition than the control condition, $p < .0001$, $d = 0.70$; and at the 2-month follow-up, $p = .0013$, $d = 0.70$.

In regard to subjective symptom reports, veterans reported a significant reduction in trauma-related symptoms on the PCL-5 upon completion of NFB versus the control condition at the endpoint assessment, $p < .0001$, $d = 0.94$; and at the 2-month follow-up, $p < .0001$, $d = 0.93$. Participants also demonstrated significantly lower scores on the PHQ-9 in the NFB condition than in the control condition at the endpoint assessment, $p < .0001$, $d = 1.23$; and at the 2-month follow-up, $p < .0001$, $d = 0.99$. Participants also reported less subjective stress on the DASS-21 following the treatment condition compared to the control condition at the end of the study, $p < .0001$, $d = 1.10$; and at the 2-month follow-up, $p < .0001$, $d = 0.84$. The participants indicated fewer general symptoms on the GSI or less severity of symptoms at the end of the study, $p < .0001$, $d = 1.11$; and at the 2-month follow-up, $p < .0001$, $d = 0.93$. See Table 2 for additional details on these analyses.

Clinical impact of an intervention can also be assessed by determining if there were clinically significant change shifts in scores on outcome measures. As seen in Table 3, there were clinically significant change scores for most of the outcome measures.

Additionally, we looked at the average difference between scores at the end of treatment and scores at the 2-month follow-up assessment to examine whether the clinically significant benefits were maintained after the conclusion of treatment (Table 4). Overall, the observed differences were not substantial based on the confidence intervals displayed.

Table 3

Average Change of Delayed Intervention Group From Its Control Group Results With Clinically Significant Change Indices for Each Measure and Percentage of Responders for Each

Assessment Tool	End of Treatment Score	Baseline Score	Average Change in Delayed Intervention Group*	Clinically Significant Change Index	Percentage of Responders (95% CI)**
HIT-6	51.8	62.6	−10.8	2.3 points	87.5 (71.0, 96.5)
TBI QOL Headache Pain	21.2	32.2	−11	7 points	68.8 (50.0, 83.9)
ISI	8.6	16.9	−8.3	3 points	68.8 (50.0, 83.9)
Neuro QOL Sleep Disturbance	16.9	25.1	−8.2	7 points	56.2 (37.7, 73.6)
QIK Test	281.4	259.3	22.1	7 points	61.3 (42.2, 78.2)
QOLIBRI	66.9	50.8	16.1 (32%)	30%	53.1 (34.7, 70.9)

Table 3

Average Change of Delayed Intervention Group From Its Control Group Results With Clinically Significant Change Indices for Each Measure and Percentage of Responders for Each

Assessment Tool	End of Treatment Score	Baseline Score	Average Change in Delayed Intervention Group*	Clinically Significant Change Index	Percentage of Responders (95% CI)**
Neuro QOL Participate	29.0	25.2	3.8	3.9 points	37.5 (21.1, 56.3)
Neuro QOL Satisfaction	28.2	23.3	4.9	3.7 points	56.2 (37.7, 73.6)
PCL-5	19.8	36.5	−16.7	10 points	59.4 (40.6, 76.3)
PHQ-9	6.1	13.0	−6.9	5 points	59.4 (40.6, 76.3)
DASS-21	10.3	22.9	−12.6	12.7 points	46.9 (29.1, 65.3)
GSI	82.0	149.7	−66.7 (45% change)	30%	68.8 (50.0, 83.9)

*Negative scores noted in this column indicate the direction of effect. Only the change score itself is relevant to this table and not the direction of the effect.

**Percentage of subjects who showed a clinically significant improvement in outcome scores at the end of the NFB phase compared with the follow-up of the control phase, with corresponding 95% Clopper–Pearson exact binomial confidence intervals. Analyses were conducted using a per-protocol approach.

Table 4

Average Difference in Outcome Scores Between 2-Month Follow-Up and the End of Treatment Phase With CI Intervals*

Assessment Tool	Average difference (95% CI)
HIT-6	2.3 (−0.9, 5.3)
TBI QOL Headache Pain	1.6 (−1.5, 4.7)
ISI	2.1 (0.5, 3.6)
Neuro QOL Sleep Disturbance	1.6 (−0.2, 3.5)
QIK-Test	−5.4 (−17.4, 6.6)
QOLIBRI	−2.9 (−7.7, 1.9)
Neuro QOL Participate	0 (−2.1, 2.1)
Neuro QOL Satisfaction	0 (−2.3, 2.3)
PCL-5	0.4 (−4.2, 5.0)
PHQ-9	0.8 (−0.6, 2.3)
DASS-21	2.5 (−0.3, 5.4)
GSI	9.2 (−5.8, 24.3)

* Difference = 2-month follow-up – end of treatment. Analyses were conducted using a per-protocol approach.

Discussion

This analysis focused on participants who completed the control and delayed intervention procedures to assess the impact of ILF NFB on symptoms commonly experienced by veterans who have experienced mTBI, headaches, sleep, and attention disorders. In addition to these specific variables of interest, additional assessment measures capture data on participants' QOL, and symptoms related to PTSD and depression. Veterans, who were originally from the control group of a larger RCT, completed a delayed ILF NFB intervention. Participants demonstrated statistically significant improvements in all areas assessed when compared to their own control group data at baseline. The associated effect sizes varied from small (attention), moderate (QOL related to life satisfaction and participation in roles), large (headache, sleep, QOL after brain injury, PTSD at follow-up, depression, anxiety, and stress and general symptoms experience), and very large (sleep) at posttreatment. Most of the comparisons demonstrated a large effect size. In addition to demonstrating practical significance, the improvements seen in the delayed intervention group show clinically significant effects. The results of delayed intervention group support the hypothesis that ILF NFB would improve in headache, sleep, and attentional symptoms above and beyond those results received while serving in the control group. Secondary outcomes measures captured broader impacts of ILF NFB on psychosocial functioning, mood, and general health, providing insight into the intervention's effect on overall well-being.

This study further validates existing research that has supported ILF NFB as an efficacious clinical intervention (Arina et al., 2022; Carlson et al., 2025; Carlson & Ross, 2021; Dobrushina et al., 2017; Legarda et al., 2022). This research study used ILF NFB successfully as an intervention for veterans with mTBI, who are well known to be a treatment-resistant group, for which effective treatments have been difficult to identify (Agimi et al., 2024). This research project also verifies that the use of the precision iterative, idiosyncratic approach to identifying each individual's ORF is an effective approach in ILF NFB. The implementation of the ILF NFB precision model by the providers, which was an individualized, precise data driven approach in determining the ORF for each participant, was an important aspect of the study as well, since finding the ORF resulted in the greatest symptom reduction by the participants.

To our knowledge, this is the only analysis of an ILF NFB delayed intervention group that was involved in a RCT. By conducting an additional analysis of control group members, subsequent exposure to ILF NFB provided another source of data that further serves to validate ILF NFB as an effective treatment. It was an ethical commitment of the investigators in this study to offer those participants randomized into the control group treatment even though it impacted time involvement and study costs. Throughout the study, the participants were encouraged to continue in treatment as usual and other treatments that may affect the study's variables of interest. Another strength of the study was the implementation of procedures to achieve an expert skill level among the ILF NFB providers, minimizing the confounding factor of provider proficiency level negatively impacting study outcomes. Even though the control group members were not mandated to continue into the delayed intervention group, most control group members choose to enter. Of note for participants who dropped out, the majority (85%) did so during the timeframe of COVID-19 (between March 2020 and May 2023). Loss of jobs, reassignments, change of schedules, and moving out of state were among the reasons for attrition. The demographic diversity of the sample, including a substantial proportion of biracial/multiracial participants, enhances the generalizability of findings to the broader veteran population. The low attrition rate and absence of intervention-related adverse events further support the feasibility and safety of ILF NFB.

A limitation of the present study's design is that the delayed intervention group had an extra 2 months of clinical contact, and continuous, therapeutic contact with a professional could have contributed to findings. There is also the potential that the expectations of participants in the intervention group were impacted by the novelty of ILF NFB technology. There is some evidence that taking part in a clinical trial using innovative technology may in and of itself bias participant expectations and thus, potentially, their outcomes (Lawton et al., 2019). While the delayed intervention group demonstrated significant improvement in symptoms over the course of study when compared to its results as a control group, results should be interpreted with these factors in mind.

Although the QIK-test measure of attention was statistically significant at end of treatment and at the 2-month follow-up, the small effect size result is of concern. This finding may be related to practice effects of completing the QIK test seven times by the participants across the course of the study. Of note,

recent research has indicated that the use of objective tests to capture attention issues in veterans with mTBI has not been found as relevant to the veteran experience as subjective measures (Ord et al., 2025).

Future research should focus on further understanding the factors that contribute to improvements seen in response to ILF NFB therapy. To explore whether and to what degree nonspecific effects of participating in this treatment impact participants' outcomes, a research design utilizing sham ILF NFB for the control condition, a technology now available, may be helpful. Given the substantial clinical effects evident in this study, fMRI studies may assist in understanding the brain connectivity pathways that may have renormalized with this treatment modality.

Based on the clinical impact observed in the present study, future research may also demonstrate utility of ILF NFB in broader populations other than veterans with mTBI in those areas where our results demonstrated potential for treatment, such as chronic sleep, headache, and attention disorders, as well as for other physiological and psychological issues that this study provided initial data.

Conclusion

ILF NFB holds promise to be a safe and effective intervention for those who continue to suffer with postconcussive symptoms of chronic headache, sleep, and attention disorders. Secondary outcomes from the present study also suggest that ILF NFB may an effective intervention for symptoms associated with depression and PTSD, in addition to having a significant positive impact on subjective QOL in veterans with mTBI. Given the absence of intervention-related adverse events and the high rate of clinically significant improvement, ILF NFB should be considered for further study and potential integration into multidisciplinary care for veterans with persistent postconcussive symptoms.

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Author Declarations

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