

Clinical Impact of Infra-Low Frequency Neurofeedback on Combat Veterans With Chronic Postconcussive Symptoms

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Background: Infra-low frequency (ILF) neurofeedback (NFB) has demonstrated efficacy in the treatment of several physical and psychological conditions, including headaches, insomnia, and attentional dysfunctions. About 20% to 40% of combat veterans who experienced concussions during recent military operations persistently experience these disorders. This secondary analysis of a randomized controlled trial (RCT) sought to evaluate the effectiveness of ILF NFB.

Methods: This RCT enrolled 87 participants to meet the goal of ≥ 36 completing the intervention (20 half-hour sessions of ILF NFB) and 36 completing control procedures (8 weekly 15-minute health-related discussions). Both groups completed 4 assessments (baseline, midpoint, end-of-treatment, and 2-month follow-up) and continued treatment as usual throughout the study. The attrition rate was 18%.

Results: Participants were 91% male with a mean age of 45

years. Effect sizes were statistically and clinically significant from baseline to end-of-treatment with Headache Impact Tool scores decreasing from 61.3 to 48.9 ($P < .001$, $d = 1.53$) and Insomnia Severity Index scores decreasing from 17.2 to 7.9 ($P < .001$, $d = 1.53$). At 2-month follow-up, although some decline was noted in headache and sleep ($P < .001$, $d = 1.14$; $P < .001$, $d = 0.97$, respectively), both scores remained statistically significant. The attention measure results did not demonstrate any significant differences. Additional variables of interest, including quality of life, depression, and posttraumatic stress disorder, had statistically and clinically significant improvements following ILF NFB.

Conclusions: ILF NFB shows promise as a safe and effective intervention for individuals experiencing persistent postconcussive symptoms of headache, insomnia and other related symptomatology.

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Traumatic brain injury (TBI) is the signature injury of post-9/11 military operations, impacting $> 441,000$ combat veterans from 2001 to 2021 and 87% diagnosed with mild TBI (mTBI).^{1,2} The most common cause of mTBI during these operations was blast exposures stemming from improvised explosive devices, rocket-propelled grenades, or land mines. mTBI was once thought to be self-limiting, lasting hours or days postinjury, but is now recognized as a complex focal and diffuse injury causing a cascade of molecular and biochemical responses with significant physiologic effects lasting for a longer duration. A significant number of combat veterans with mTBI (23%-48%) experience long-standing postconcussive symptoms (PCSs) for many years postinjury.³⁻⁵

Developing and implementing strategies to reduce persistent symptoms associated with mTBI is of critical importance. Veterans diagnosed with mTBI and experiencing PCSs present ongoing treatment challenges to the health care system due to limited or suboptimal treatment options.^{6,7} According to the 2021 US Department of Veterans Affairs (VA) and US Department of Defense (DoD) clinical guidelines for postacute mTBI, treatment for PCSs should be symptom focused.^{8,9} For instance, veterans with migraine

headaches associated with mTBIs are often treated with abortive agents (eg, triptans) and preventive medications (eg, anticonvulsants and tricyclics).¹⁰ Cognitive dysfunction and insomnia are treated with cognitive rehabilitation programs, cognitive behavioral therapy, occupational therapy, and medications (eg, hypnotics for insomnia).^{11,12} The 2021 VA/DoD guidelines note that veteran and military focus groups described greater success with nonpharmacologic treatments than with pharmacologic treatments.⁸ The VA launched an enterprise-wide Whole Health Service program with the requirement that complementary and integrative health approaches must be available to veterans.¹³ As a nonpharmacologic, integrative, and noninvasive modality, neurofeedback (NFB) supports the VA Whole Health initiative and veterans' preferences for integrative treatments.¹⁴

NEUROFEEDBACK

Rather than a symptom management approach, Defina et al described the possibilities of brain repair in TBI by treatments to enhance neuroplasticity, thereby establishing a more normalized or stable brain environment and enabling the brain to reorganize itself and function more normally.¹⁵ NFB has been shown to influence neuroplasticity,¹⁶ as

TABLE 1. Descriptions of Primary Assessment Measures

Name	Description	Score range (significant score shift)	Interpretation
Headache Impact Test (HIT-6) ³⁶	6-question tool designed to describe and communicate the way people feel and what they cannot do because of headaches	36-78 (2.3) ³⁷	Lower scores indicate less headache impact
TBI-QOL Headache Pain item short form ³⁸	10-item measure that assesses headache pain over past week	10-50 (7) ³⁹	Lower scores indicate less pain
Insomnia Severity Index (ISI) ⁴⁰	7-question tool assessing the severity, perception, and consequences of the person's insomnia over the past 2 weeks	0-28 (3) ^{a,41}	Lower scores indicate less insomnia experience
Neuro-QOL Sleep Disturbance short form ⁴²	8-item form that measures a person's reported sleep disturbance over the past 7 days	8-40 (7) ⁴³	Lower scores indicate less disturbance
QIKtest Continuous Performance Tests (QIKtest) ⁴⁴	21-minute computerized visual performance test to assess attention and impulse control and speed and consistency of response	40-160 (7) ⁴⁴	Higher scores suggest better attention

Abbreviations: Neuro-QOL, Quality of Life in Neurological Disorders; TBI-QOL, Traumatic Brain Injury-Quality of Life.

evident in microstructural changes in white and gray matter¹⁷ and its ability to contribute to functional rehabilitation by restoring connectivity in specific areas of the brain that may have been impaired.¹⁸ The benefits of neuroenhancement strategies include potentially reduced pain for patients with mTBI and improved quality of life (QOL).¹⁹

NFB assists individuals by helping them become more aware of and self-regulate their physiology.^{20,21} Because there are several types of NFB (eg, quantitative electroencephalography, Z-scored, α - θ) that differ in terms of equipment, mechanism of action, focus, and patient and clinician procedures, it is important to note that this study used a novel technologically advanced form of NFB, referred to as infra-low frequency (ILF) NFB. It works by reflecting a person's brain wave activity via conventional electroencephalography back to the person through the visual cortex, thus providing relevant information to which the brain responds to improve core state regulation.²²

In 2006, ILF NFB developers sought to extend NFB capability into the slow cortical potential domain (< 0.1 Hz) and then gradually extended to lower frequencies on the basis of favorable clinical responses.^{22,23} In 2017, the technology reached an ILF capacity that appeared to be helpful for several clinical issues. These developments depended on instrumentation capable of low-noise signal detection down to the lowest frequency of interest. Instrumentation was developed for the purpose (eg, Bee Medic Cynet NFB).

Although mTBI has been a clinical focus in NFB since the 1980s, there are few published studies demonstrating the efficacy of ILF NFB relating to the PCSs of interest in this study, and 2 suggested ILF NFB positively affected change in PCS severity.^{24,25} Other studies found that ILF NFB decreased incidence of migraines and tension-type headaches.^{26,27} However, the findings of these studies had limited generalizability due to methodologic limitations, such as selection bias and small sample sizes.²⁴⁻²⁷ Of importance to this article, there are also several publications on the efficacy of ILF NFB in clinical settings.²⁸⁻³³

This article presents the second analysis of data from veterans who completed ILF NFB intervention and control group procedures during a 5-year randomized controlled trial (RCT). The RCT included veterans who experienced an mTBI while participating in post-9/11 military operations to evaluate the impact of ILF NFB on chronic PCSs, including headache, insomnia, and attention dysfunction. Initial results of this trial demonstrated significant differences between the intervention and control groups with strong effect sizes on all outcome measures at the end of treatment.³⁴

METHODS

Participants included male and nonpregnant female veterans with a diagnosed mTBI during post-9/11 military operations; aged 18 to 65 years; reports of persistent (ie, > 3 months in duration) headaches, insomnia, and attention difficulties; and able

to read and write English, comprehend what is read, and follow directions. mTBI diagnosis was verified for each veteran via the electronic health record. Patients were excluded if they 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.³⁵

Recruitment efforts included: (1) letters sent to eligible veterans with mTBI who were identified by clinical informatics data after waiver of Health Insurance Portability and Accountability Act was obtained; veterans could contact the research team directly or the research team would call the veteran 2 weeks after the letter was sent; (2) veterans could be referred by a clinician; and (3) veterans could self-refer based on flyers and other study marketing materials.

The study was conducted from 2019 to 2024 at Spark M. Matsunaga VA Medical Center, in Honolulu, Hawaii. Four private research spaces in compliance with human research standards were used for consent, treatment, and assessment.

Consenting Procedure and Randomization

The privacy rights of potential participants were observed, and interested veterans who met the eligibility criteria underwent an informed consent procedure and were administered the Columbia-Suicide Severity Rating Scale.³⁵ Those veterans not indicating active suicidal intent were randomized into the intervention or control group. Once randomized, the participant was enrolled and scheduled for baseline assessment.

All procedures of this study were performed in adherence with relevant laws and institutional guidelines. The study was reviewed and approved by the VA Pacific Islands Health Care System Institutional Review Board (#2019-06-JC/Promise 0003).

Outcome Measures

The outcome measures were administered at baseline, midpoint (3-7 weeks), end of treatment (6-12 weeks), and at a 2-month follow-up appointment with the research assistant or project coordinator.

The primary outcome measures include the Headache Impact Test (HIT-6), TBI-QOL Headache Pain item short form, In-

somnia Severity Index (ISI), Quality of Life in Neurological Disorders (Neuro-QOL) Sleep Disturbance short form, and attention measure: QIKtest Continuous Performance Test (QIKtest) (Table 1).³⁶⁻⁴⁴

Secondary outcome measures included QOL After Brain Injury (QOLIBRI), Neuro-QOL Satisfaction With Roles/Activities short form (Neuro-QOL Satisfaction), Neuro-QOL Ability to Participate in Roles/Activities short form (Neuro-QOL Participate), Depression Anxiety Stress Scales (DASS-21), Patient Health Questionnaire-9 (PHQ-9), Posttraumatic Stress Disorder (PTSD) Checklist for DSM-5 (PCL-5), and the General Symptom Inventory (eAppendix 1, available at doi:10.12788/fp.0689).^{39,42,45-52}

Sample

Seventy-two participants (36 in each group) were needed to have adequate statistical power for the analysis. Presuming attrition, the goal was to recruit 100 veterans. Literature on NFB studies of patients with mTBI have reported dropout rates ranging from 10% to 30%.^{53,54} 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 SDs with a power of 80% in the NFB intervention group compared with the control group using a 2-tailed significance level of 0.05.

Control Group

Following baseline assessment, control group participants received 8 phone calls (1 call/wk) from 1 of 4 clinical investigators over 8 to 10 weeks. During each 15-minute call, 1 of the following health topics was discussed: sleep hygiene, basic nutritional concepts, beverage choices, positive thinking, thought reframing, fitness, daily calming activity, and enhancement of focus strategies. A script for each topic was used to guide each call.

Intervention Group

Following baseline assessment, intervention group participants completed 20 half-hour ILF NFB sessions, typically receiving 3 sessions per week over an 8- to 10-week period. ILF NFB treatments were administered by 1 of 4 licensed health care employees who

had received substantial ILF NFB training and achieved a skill reliability index score of 0.95, ensuring the skill level of the ILF NFB providers was equal. A script was used by the ILF NFB providers during the ILF NFB sessions to keep the interaction approach consistent with all participants.

All procedures were explained in advance to participants and voluntary participation affirmed. At the first session, participants filled out a clinical symptom checklist of 5 symptoms (eAppendix 1).^{39,42,45-49} The initial rating on the symptom checklist was 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' primary or secondary outcome measures data during the study, so these recurring clinical symptom checklist ratings, as well as other feedback provided by participants on their experience within and between sessions, were the clinical data used to make decisions about ILF NFB treatment protocol.

The Othmer Optimal Response Frequency (ORF) protocol was used for participants in this study.⁵⁵ Through an iterative process, ORF protocol establishes the specific frequency point along the 0.000001 mHz to 0.1 Hz continuum, which is optimal to diminish symptoms experienced in real-time during the session (eg, tension or pain in shoulders; racing thoughts).

During each ILF NFB session, participants were seated comfortably and encouraged to look at the feedback screen. The moving images on the game screen provided almost instantaneous feedback (within 500 ms) to participants about their brain functioning, as ascertained by electrodes placed on the scalp as dictated by study protocol.⁵⁶ A standardized protocol for site placement was used beginning with T3-T4, followed by the weekly addition of a site as tolerated in the following sequence: T4-P4, FP2-T4, and FP1-T4. More information about the ILF NFB procedures are outlined in the report of the pilot study and RCT initial results.^{22,34}

Statistical Analysis

Eighty-seven participants were randomized, with 43 assigned to the intervention

group and 44 to the control group to achieve the enrollment goal of ≥ 36 participants in each group. This report is the second analysis of data from this RCT that employed a per-protocol approach, analyzing a subset of participants who fully adhered to the study protocol and completed all study procedures. Outcome scores at baseline, midpoint, end of treatment, and 2-month follow-up were summarized as means with corresponding 95% CIs. Group comparisons at the end of treatment and 2-month follow-up time points were conducted using 2-sample *t* tests. All statistical tests were 2-sided with a significance level of .05 (Type I error rate). SAS software version 9.4 Maintenance 8 was used for statistical analysis. Cohen *d* analyses were used for effect sizes.

RESULTS

Seventy-four participants fully adhered to the study protocol and were included in the present analyses, with 38 in the control group and 36 in the intervention group. eAppendix 2 (available at doi:10.12788/fp.0689) depicts the flow of participants through this study. There were no adverse events related to treatment, and the 13 participants who withdrew typically reported difficulty with scheduling or transportation as the primary reason. This study also took place during the COVID-19 pandemic, which likely had some impact on enrollment; participants were differentially impacted by changes in employment and moves to the continental United States.

Participants were aged 30 to 60 years (mean [SD], 45.4 [8.0]). Most participants (90.5%) were male, and multiracial and White were the most common racial identities (Table 2). Participant characteristics were largely balanced across randomized groups. Similarly, test scores on the primary variables of interest in this study and secondary clinical variables assessed were comparable across participants (Table 3).

Primary Variables of Interest Analyses

This study's hypothesis was that those who completed ILF NFB treatment per protocol would demonstrate statistically significant improvement in symptoms related to headaches, sleep disturbance, and difficulty with attention when com-

TABLE 2. Baseline Participant Characteristics

	Control (n = 38)	ILF NFB (n = 36)
Age, mean (SD)	45.5 (8.7)	45.9 (7.9)
Male sex, No. (%)	34 (89.5)	33 (91.7)
Self-identified ethnicity, No. (%)		
Black	7 (18.4)	4 (11.1)
White	9 (23.7)	11 (30.6)
Asian	5 (13.2)	4 (11.1)
Native American	0 (0)	1 (2.8)
Hispanic	2 (5.3)	7 (19.4)
Hawaiian/Pacific Islander	1 (2.6)	2 (5.6)
Multiracial	12 (31.6)	7 (19.4)
Did not disclose/unknown	2 (5.3)	0 (0)

Abbreviations: ILF, infra-low frequency; NFB, neurofeedback.

pared with veterans in the control group. This hypothesis was partially supported. A 2-sample *t* test showed that veterans in the intervention group demonstrated significant improvement in headache symptoms compared with veterans in the control group on the HIT-6 at the end-of-treatment ($P < .001$, $d = 1.53$) and 2-month follow-up assessment ($P < .001$, $d = 1.14$). This pattern also was consistent with the TBI-QOL Headache Pain item short form, with veterans in the intervention group showing improvement beyond those in the control group at the end-of-treatment ($P < .001$, $d = 0.89$) and 2-month follow-up assessment ($P < .001$, $d = 0.83$). Two-sample *t* tests also demonstrated significant improvement in subjective reports of sleep; those in the intervention group had significantly lower scores on the ISI at the end-of-study ($P < .001$, $d = 1.53$) and 2-month follow-up assessment ($P < .001$, $d = 0.97$). This pattern also held true for the Neuro-QOL Sleep Disturbance short form subtest, which demonstrated significantly more improvement in the intervention group compared with the control group at the end-of-study ($P < .001$, $d = 0.97$) and 2-month follow-up assessment ($P < .001$, $d = 0.92$). The hypothesis regarding significant improvement in attention was not supported by the present results. A 2-sample *t* test found no significant difference between performance on the QIKtest for veterans in the intervention group vs the control group at the end-of-study ($P = .40$, $d = 0.19$) or the 2-month follow-up ($P = .43$, $d = 0.20$) (eAppendix 3, available at doi:10.12788/fp.0689).

Secondary Variables of Interest Analysis

Secondary variables examined differences in QOL, PTSD, depressive symptoms, and general symptoms reported between veterans in the intervention and control groups. Results demonstrated that veterans in the intervention group showed improvement above and beyond those in the control group on all measures. In regard to QOL, veterans in the intervention group had significantly higher scores on the Neuro-QOL Participate subtest than those in the control group at the end-of-study ($P = .01$, $d = 0.89$) and 2-month follow-up assessment ($P < .001$, $d = 0.62$). A similar pattern was found for the Neuro-QOL Satisfaction subtest, with veterans in the intervention group showing significantly higher scores than those in the control group at the end-of-study ($P = .001$, $d = 0.95$) and 2-month follow-up assessment ($P < .001$, $d = 0.62$). This also held true on the QOLIBRI, with veterans in the intervention group demonstrating significantly higher scores than those in the control group at the end-of-study ($P = .001$, $d = 0.92$) and 2-month follow-up assessment ($P < .001$, $d = 0.66$).

Veterans in the intervention group had significantly lower scores on the PCL-5 than those in the control group at the end-of-study ($P = .003$, $d = 0.78$) and 2-month follow-up assessment ($P = .001$, $d = 0.72$). Veterans in the intervention group also had significantly lower scores on the PHQ-9 than those in the control group at the end-of-study ($P < .001$, $d = 0.98$) and 2-month follow-up assessment ($P < .001$, $d = 0.83$). Veterans in the intervention group had significantly lower scores on the DASS-21 than those in the control group at the end-of-study ($P = .002$, $d = 0.80$) and 2-month follow-up assessment ($P = .001$, $d = 0.77$). They also had significantly lower scores on the General Symptom Inventory than those in the control group at the end-of-study ($P = .02$, $d = 0.75$) and 2-month follow-up assessment ($P = .002$, $d = 0.57$). A clinically significant shift of score occurred for each of the measures except DASS-21 (eAppendix 3). eAppendix 4 (available at doi:10.12788/fp.0689) depicts the change in scores for the intervention group at the end of treatment and the clinically significant shift score of each measure.

TABLE 3. Baseline Test Scores

Measure	Control (n = 38)	ILF NFB (n = 36)
Primary variables of interest, mean (SD)		
Headache Impact Test (HIT-6)	62.7 (5.4)	61.1 (9.2)
TBI-QOL Headache Pain item short form	31.2 (8.2)	31.4 (10.6)
Insomnia Severity Index (ISI)	18.1 (5.8)	18.8 (4.6)
Neuro-QOL Sleep Disturbance short form	25.3 (5.7)	25.4 (6.7)
QIKtest Continuous Performance Test	75.7 (18.0)	70.7 (16.3)
Secondary variables of interest, mean (SD)		
Neuro-QOL Ability to Participate in Roles/Activities short form	25 (5.3)	25.4 (7)
Neuro-QOL Satisfaction With Roles/Activities short form	22.7 (5.4)	23.4 (7.5)
Quality of Life After Brain Injury (QOLIBRI)	48.4 (15.7)	48.6 (17)
Posttraumatic Stress Disorder Checklist for <i>DSM-5</i> (PCL-5)	38.5 (18.2)	38.5 (19.1)
Patient Health Questionnaire-9 (PHQ-9)	13.6 (5.1)	13.7 (6.6)
Depression Anxiety Stress Scales (DASS-21)	21.9 (10.7)	22.6 (14.2)
General Symptom Inventory	149.8 (48.4)	159.5 (79.3)

Abbreviation: ILF, infra-low frequency.
 Neuro-QOL, Quality of Life in Neurological Disorders; NFB, neurofeedback; TBI-QOL, Traumatic Brain Injury-Quality of Life.

DISCUSSION

The results of this RCT revealed a promising impact of ILF NFB on the commonly experienced persistent PCSs of headaches and disrupted sleep. Veterans in the intervention group demonstrated statistically significant improvement in headache symptoms compared with veterans in the control group when assessed at the end of treatment and during a 2-month follow-up. The statistical significance of these improvements was also supported by large or very large effect sizes. In addition to these primary variables of interest, veterans in the intervention group notably demonstrated significant improvement compared with those in the control group in a number of secondary clinical measures, including QOL, traumatic stress-related symptoms, depressive symptoms, and general symptom report. The clinical impact was further supported by the clinically relevant shift in scores in the intervention group.

The data did not support the hypothesis that attention concerns would show significant improvement following ILF NFB. Performance on an attention measure did not differ significantly between groups at either the end-of-treatment or 2-month follow-up assessment. The QIKtest, a continuous performance test used to measure attention, was a go/no-go task and calculated based on a combination of various types of errors and outlier responses. The stimulus for this task is a series of computerized, blinking lights, for which participants are tasked with dis-

criminating targets and nontargets under time pressure. However, the order of the stimuli are consistent across administrations, rather than being randomized, introducing a potential confound of practice effects on this task since patients were administered the QIKtest 3 times in a 2-month period and again 2 months later. Veterans in the control group notably improved in their average performance of this task from baseline to the endpoint of their treatment participation and demonstrated further improvement at the 2-month follow-up assessment; this pattern would be consistent with potential practice effects and warrants caution in its interpretation for both groups.

Previously published ILF NFB clinical studies that used the QIKtest and found positive results were mostly conducted among children and teen populations across longer treatment periods. This research may indicate the QIKtest is not an appropriate measure to assess adults who have specialized training in responding to stimuli (ie, trained military personnel). This suggests the concept of attention dysfunction experienced by veterans and the best method to measure it may need to be explored further. This construct may not be related to the focus and skill in prolonged attention needed in selecting go/no-go tasks, but rather related to a broader conceptual basis involving memory, recall, clarity of rational thought, and decision-making impacted by the mTBI. For instance, a study among combat veterans with mTBI

and PTSD found that performance on objective cognitive measures did not significantly correlate with their subjective reports of cognitive difficulties.⁵⁷ This reflects the pattern of the present study, in which subjective reports of attention improved over time on the clinical symptom checklist filled out by participants at each session, but the objective measure did not. The mean attention dysfunction score was 6 at session 1 and 1 to 2 at session 20 (lower scores are better on a 10-point scale).

Strengths and Limitations

This study presents results stemming from the first RCT examining clinical effectiveness of ILF NFB in a VA setting for veterans with diagnoses of mTBI. The study design shows promising external validity. Veterans were able to participate in a treatment consisting of 20 sessions over a period of typically 8 to 10 weeks, entailing 2 to 3 sessions per week, with an attrition of only 18% over the course of the study. Notably, attrition rates may have been impacted by the time course of the study, which was recruiting and running participants throughout the COVID-19 pandemic (March 2020 to May 2023). No attrition was due to the intervention itself, and no adverse reactions to ILF NFB were reported during the course of the study. Other strengths of the study include the ethnically and racially diverse participants, representative of the population of veterans in Hawaii. Additionally, all ILF NFB providers underwent supervised ILF NFB training and achieved a skill reliability index score of 0.95 prior to providing ILF NFB to the intervention group.

This study was not blinded. Neither veterans nor ILF NFB providers were blinded and were therefore aware of the randomly assigned groups. Research assistants administering the periodic assessments were meant to be blinded to condition by design; however, as the study progressed, a research assistant became unintentionally aware of each study participant's condition based on required documentation in the veteran's health records; more notes were present for those in the intervention group (20 specialist notes) than the control group (8 notes). While the presence of a control group represents a strength relative to much of the existing ILF

NFB literature, the control group in this case did not account for the total time spent with the researchers. Participants in the intervention group met with researchers for 20 total sessions as opposed to 8 telephone calls. Therefore, the study design cannot fully rule out the differential impact of demand characteristics between the 2 groups, nor can it fully address or rule out the impact of differential motivation and expectations between groups. There is also evidence that technological innovation can influence the expectations of research participants, meaning that the intervention group may have been unduly influenced by the novelty of the ILF NFB technology, to which the control group did not have exposure.⁵⁸

A second attention measure for this study would have been beneficial, perhaps in identifying true change in attention ability or providing more insight into finding better methods to assess attention among veterans with mTBI. ILF NFB demonstrated significant impact across multiple outcome measures of clinical relevance for veterans diagnosed with mTBI, including the primary outcome variables of headache and sleep. The strength of the improvements seen in these areas, supported by large practical effects as well as veterans' subjective reports, indicates much promise. Follow-up studies may also focus on the potential effectiveness of ILF NFB as a treatment of the secondary concerns measured in this study, including traumatic stress-related and depressive symptoms, and may explore the added benefit, if any, of ILF NFB alongside other evidence-based treatments for traumatic stress-related and mood disorders (eg, cognitive behavioral therapy). Using functional magnetic resonance imaging before and after assessments to determine actual brain enhancement with ILF NFB for certain disorders in which a brain signature exists (ie, migraine) should be explored. Further examination of ILF NFB as an intervention for attention may also be warranted, using more effective measures of attention in the population of veterans with mTBI, given the concerns noted earlier. Future research on this topic will need to clearly define attention in relation to the veteran experience and use relevant measures.

CONCLUSIONS

This study supports ILF NFB as a safe, non-invasive, nonpharmacologic treatment that may be effective in addressing the complex clinical concerns of veterans diagnosed with mTBI, a population for whom effective treatments have been difficult to identify. This intervention can provide veterans with a desirable and effective nonpharmacologic alternative in their care.

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Disclaimer

The opinions expressed herein are those of the authors and do not necessarily reflect those of *Federal Practitioner*, Frontline Medical Communications Inc., the US Government, or any of its agencies.

Ethics and consent

All procedures of this study were performed in compliance with relevant laws and institutional guidelines and was approved by the Veterans Affairs Pacific Islands Health Care System Institutional Review Board (#2019-06-JC/Promise 0003).

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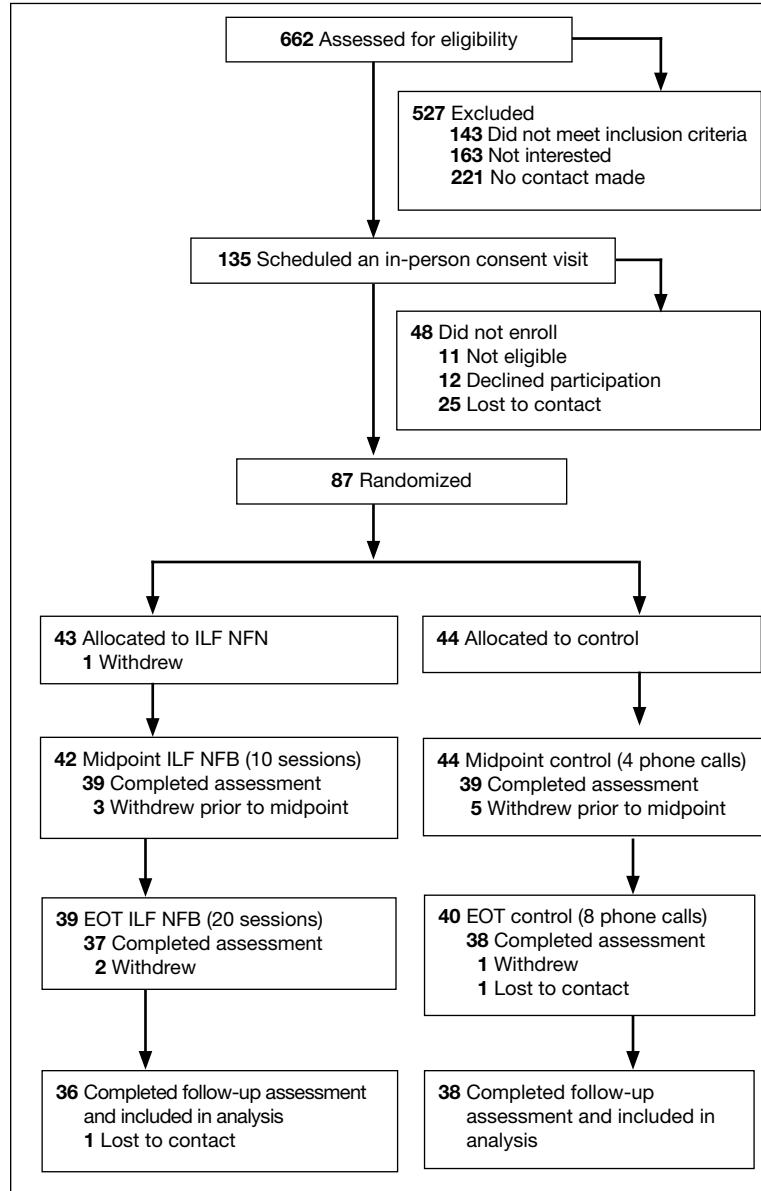
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eAPPENDIX 1. Description of Secondary and Ancillary Measures

Secondary assessment outcome tools			
No.	Name	Description	Interpretation
1	QOL After Brain Injury (QOLIBRI) ⁴⁵	37-item instrument consisting of 6 scales measuring cognition, self, daily life and autonomy, social relationships, emotions, and physical problems; designed to measure QOL specifically for TBI Score Range: 0-100 Clinically Significant Score Shift: 30% ⁴⁵	Higher scores indicate greater QOL
2	Neuro-QOL Satisfaction With Roles/Activities short form ⁴²	8-item instrument that measures a person’s satisfaction with social roles and activities over the past 7 days Score Range: 8-40 Clinically Significant Score Shift: 3.7 points ³⁹	Higher scores indicate greater satisfaction
3	Neuro-QOL Ability to Participate in Roles/Activities short form ⁴²	8-item instrument that measures a person’s perception of their capability to participate in social roles and activities in the past 7 days Score Range: 8-40 Clinically Significant Score Shift: 3.9 points ³⁹	Higher scores suggest an increased ability to participate
4	Patient Health Questionnaire-9 (PHQ-9) ⁴⁶	9-item instrument that assesses depression Scores Range: 0-27 (10 suggests moderate depression) Clinically Significant Score Shift: 5 points ⁴⁷	Lower scores suggest less depression
5	PTSD Checklist for DSM-5 (PCL-5) ⁴⁸	20-item instrument that assesses the symptoms of PTSD in the past month Score Range: 0-80 (31-33 suggests probable PTSD) Clinically Significant Score Shift: 10 points ⁴⁹	Lower scores indicate fewer PTSD symptoms
6	Depression Anxiety Stress Scales (DASS-21) ⁵⁰	21-item instrument that assesses depressive, anxious, and stress symptoms over the past week Score Range: 0-63 (17-20, mild distress; 21-25, moderate distress; 26-29, severe distress; ≥ 30, extremely severe distress) Clinically Significant Score Shift: 12.7 points ⁵¹	Lower scores suggest less distress
7	General Symptom Inventory ⁵²	117-item instrument that assesses general health symptoms over the past month; each item is a 5-point scale (0-4) Score Range: 0-464 Clinically Significant Score Shift: 30% ⁵²	Lower scores suggest less severity or less frequency
Ancillary assessment tools			
No.	Name	Description	Interpretation
1	Demographic Data Form	Age, sex, current medical diagnoses, relevant symptoms to study, current medications, current therapeutic classes and treatments, medical board status, and previous experience with biofeedback	Provides key information about study participants
2	Session 5-Clinical Symptom Checklist	An abbreviated symptom checklist used at each session to assist with treatment decisions. In this study, the first 3 symptoms were headache, insomnia, and attention issues. Participants chose 2 other symptoms that were most significant to them. At the beginning of each session, the participant scores each symptom on an 0-10 scale with 10 being the worst possible score.	Lower scores suggest less severity or less frequency

Abbreviations: Neuro-QOL, Quality of Life in Neurological Disorders; PTSD, posttraumatic stress disorder; QOL, quality of life; TBI, traumatic brain injury.



eAPPENDIX 2. CONSORT Participant Flow Diagram

Abbreviations: EOT, end-of-treatment; ILF, infra-low frequency; NFB, neurofeedback.

eAPPENDIX 3. End-of-Treatment and 2-Month Follow-up Test Scores^a

Score	Time	Control, mean (95% CI)	ILF NFB, mean (95% CI)	P value	d ^b
Primary variables of interest					
HIT-6	End of treatment	61.3 (59.6, 63)	48.9 (45.4, 52.4)	< .001	1.53
	2-mo follow-up	62.6 (60.2, 65)	51.8 (48, 55.6)	< .001	1.14
TBI QOL Headache Pain	End of treatment	28.2 (24.9, 31.5)	18.9 (15.3, 22.5)	< .001	0.89
	2-mo follow-up	32.2 (28.8, 35.6)	22.8 (18.6, 27.0)	< .001	0.83
ISI	End of treatment	17.2 (15.6, 18.8)	7.9 (5.5, 10.3)	< .001	1.53
	2-mo follow-up	16.9 (15.0, 18.8)	10.3 (7.7, 12.9)	< .001	0.97
Neuro QOL Sleep Disturbance	End of treatment	23.8 (21.8, 25.8)	16.6 (13.7, 19.5)	< .001	0.97
	2-mo follow-up	25.1 (23.3, 26.9)	18.5 (15.6, 21.4)	< .001	0.92
QIKtest	End of treatment	79.8 (72.2, 87.4)	84.3 (75.6, 93.0)	.40	0.19
	2-mo follow-up	81.7 (74.0, 89.4)	77.4 (70.5, 84.3)	.43	0.20
Secondary variables of interest					
Neuro QOL Participate	End of treatment	24.8 (23.0, 26.6)	30.9 (28.2, 33.6)	.001	0.89
	2-mo follow-up	25.2 (23.4, 27)	29.5 (26.7, 32.3)	< .001	0.62
Neuro QOL Satisfaction	End of treatment	23.2 (21.2, 25.2)	30.7 (27.6, 33.8)	.01	0.95
	2-mo follow-up	23.3 (21.3, 25.3)	28.2 (25.0, 31.4)	< .001	0.62
QOLIBRI	End of treatment	50.3 (44.7, 55.9)	68.9 (61.0, 76.8)	.007	0.92
	2-mo follow-up	50.8 (45.4, 56.2)	64.6 (56.1, 73.1)	< .001	0.66
PCL-5	End of treatment	33.0 (27.5, 38.5)	19.0 (12.5, 25.5)	.003	0.78
	2-mo follow-up	36.5 (30.6, 42.4)	22.9 (16.1, 29.7)	.001	0.72
PHQ-9	End of treatment	12.0 (10.2, 13.8)	5.8 (3.4, 8.2)	< .001	0.98
	2-mo follow-up	13.0 (11.0, 15.0)	7.5 (5.1, 9.9)	< .001	0.83
DASS-21	End of treatment	19.7 (15.9, 23.5)	10.3 (6.2, 14.4)	.002	0.80
	2-mo follow-up	22.9 (19.0, 26.8)	13.2 (8.6, 17.8)	.001	0.77
GSI	End of treatment	139.7 (120.3, 159.1)	83.2 (53.3, 113.1)	.02	0.75
	2-mo follow-up	149.7 (130.5, 168.9)	104.2 (71.1, 137.3)	.002	0.57

Abbreviations: DASS-21, Depression Anxiety Stress Scales; GSI, General Symptom Inventory; HIT-6, Headache Impact Test; ILF, infra-low frequency; ISI, Insomnia Severity Index; Neuro-QOL, Quality of Life in Neurological Disorders; NFB, neurofeedback; PCL-5, Posttraumatic Stress Disorder Checklist for *DSM-5*; PHQ-9, Patient Health Questionnaire; QOL, quality of life; QOLIBRI, Quality of Life After Brain Injury; TBI, traumatic brain injury.

^aAnalyses were performed using complete cases, and comparisons using 2 sample *t* tests; group comparisons were performed at the end and follow-up time points, with *P* values and *d* effect sizes.

^bEffect size: 0-0.2, not relevant; 0.2-0.5, small; 0.5-0.8, moderate; 0.8-1.3, large; > 1.3, very large.

eAPPENDIX 4. Mean Change for ILF NFB Group and Clinically Significant Change Indices^a

Assessment	End-of-treatment	Baseline	Mean change in ILF NFB group (% change) ^a	Clinically significant change index
HIT-6	48.9	61.1	-12.2	2.3 points
TBI QOL Headache Pain	18.9	31.4	-12.5	7 points
ISI	7.9	18.8	-10.9	3 points
QIKtest	84.3	70.7	13.6	7 points
Neuro-QOL Participate	30.9	25.4	5.5	3.9 points
Neuro-QOL Satisfaction	30.7	23.4	7.3	3.7 points
Neuro-QOL Sleep Disturbance	16.6	25.4	-8.8	7 points
QOLIBRI	68.9	48.6	20.3 (30)	30%
PCL-5	19.0	38.5	-19.5	10 points
PHQ-9	5.8	13.7	-7.9	5 points
DASS-21	10.3	22.6	-12.3	12.7 points
GSI	83.2	159.5	-76.3 (48)	30%

^aNegative scores indicate the direction of effect.

Abbreviations: DASS-21, Depression Anxiety Stress Scales; GSI, General Symptom Inventory; HIT-6, Headache Impact Test; ILF, infra-low frequency; ISI, Insomnia Severity Index; Neuro-QOL, Quality of Life in Neurological Disorders; NFB, neurofeedback; PCL-5, Posttraumatic Stress Disorder Checklist for DSM-5; PHQ-9, Patient Health Questionnaire; QOL, quality of life; QOLIBRI, Quality of Life After Brain Injury; TBI, traumatic brain injury.