

Documenting the effects of non-invasive prefrontal pIR HEG neurofeedback in the treatment of common mental health problems

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Abstract: Clients with mixed diagnoses were provided pIR HEG neurofeedback in a mental health private practice treatment setting. This is the first formally documented investigation of pIR HEG neurofeedback applied to a mental health population. Both qualitative and quantitative data was collected. Results from 66 clients showed that 5 sessions of neurofeedback resulted in statistically significant changes in anxiety, depression, limbic overload, and coping self-efficacy. For clients who completed 10 or 15 sessions, results showed robust changes in anxiety, depression, limbic overload, general self-efficacy, coping self-efficacy, and dissociation. The impact of neurofeedback on self-efficacy is discussed as well as limitations and implications for future research.

Key words: neurofeedback, pIR HEG, prefrontal cortex (PFC), self-efficacy, data-driven practice, limbic overload

Technology has been suggested as a mechanism to influence the accessibility, efficiency, and effectiveness of mental health care (Magnavita, 2018). At least 20% of people in the United States are currently suffering with a mental health disorder and almost half of all people will suffer with mental health difficulties in their lifetime. In assessing the impact of the COVID-19 pandemic, 41% of 5,500 adults surveyed in 2020 reported having an adverse mental health impact and an alarming 11% had considered suicide in the last month (Czeisler et al., 2020). The full mental health impact of a post pandemic world is still filtering into view with scores of people struggling with anxiety, social isolation, financial difficulties, COVID-related medical trauma, and ongoing stress about gun violence, the environment, and the post pandemic geopolitical state. With telehealth sessions and health-related digital apps becoming commonplace, the integration of technology into mental health services is inevitable. Further understanding technology's influence on the efficiency and effectiveness of services in this time of extensive need has become critical. This clinical program evaluation study examines the use of non-invasive prefrontal cortex neurofeedback to treat common mental health difficulties.

Neurofeedback technology represents a different type of mental health treatment. The last fifty years in the mental health field has been dominated by the innovation of psychiatric medication and cognitive behavioral psychotherapy approaches. Although evidence from many studies show that anti-depressants and psychotherapy produce a reliable small treatment effect over placebo, we know that many people do not get better from these traditional treatments. A twelve-year prospective study estimated that in depression, ninety percent of people have persistent symptoms despite treatment (Judd et al., 1998). Many people do not have access to treatment that is delivered systematically or optimally, thereby reducing an already small margin of effectiveness. In addition, side effects of medications and the difficulties clients report in finding a comfortable psychotherapy fit can be deterrents to people receiving relief from these treatments. From the clients' perspective, neurofeedback presents a notably different method and if shown to be useful, such novelty can be attractive to those who have not responded or benefitted enough from other approaches.

As an alternative treatment, neurofeedback is non-invasive and without the systemic side effects of psychiatric medication. Unlike psychotherapy, it does not rely on the person's interest or ability to work out problems through verbal communication. Neurofeedback works through implicit learning in the targeted brain area which results in new automatic capacity and function associated with that brain region. This is notably different from the explicit teaching of emotion regulation skills in psychotherapy. Explicit teaching of skills requires clients to learn, remember, and choose to implement skills when their brains are reacting emotionally. In addition, this way of explicitly teaching skills is mostly done in the context of clients' past coping difficulties. In neurofeedback, clients learn through observing their new abilities and behavioral accomplishments. In this way, neurofeedback empowers clients and instigates a natural openness and efficacy around emotional skills.

Theoretically, neurofeedback can help across diagnoses through influencing the executive brain, the prefrontal cortex (PFC). As the brain evolved over time, the emphasis shifted from a

brain with rigid, fixed functions to one that is capable of flexible adaptation. Although neurofeedback systems target a variety of brain areas, most approaches show frontal changes regardless of which brain area is targeted. The PFC's role is one of oversight, coordination, inhibition, and integration (Goldberg, 2009). Given its role, the PFC must be malleable. Activation of the PFC relates to the mental and behavioral capacity for rational thinking, self-awareness, initiation of action, integration of emotion and rational thought, and inhibition of stress reactivity. When the PFC is dominant, the limbic system becomes less dominant. The amygdala, the brain's threat detector, becomes less active when the prefrontal area is more active. By instigating change in the PFC, we target a process of greater self-regulation that may result in amelioration of symptoms and improved executive capacity across mental health diagnoses.

EEG-based neurofeedback has been around since the 1960's. Despite being a diverse and misunderstood field, several key studies show the importance of a re-examination of the utility of neurofeedback in the current demand for treating unprecedented numbers of people struggling with mental health conditions. In 2020, Yu and colleagues conducted a randomized, controlled trial (RCT) of neurofeedback in the treatment of depression targeting peak alpha frequency activation in the PFC. They showed that with 20 neurofeedback sessions, the treatment group had significant improvement in executive function and a corresponding decrease in rumination and depression. They posited that with greater PFC activation, it is easier to inhibit negative ruminative thinking resulting in a decrease in depression. A landmark study by Bessel van der Kolk et al. (2016) showed significant results for EEG neurofeedback applied to those with chronic PTSD (where there was no clinical improvement for 6 months). In recounting the results of the study in *The Body Keeps the Score*, van der Kolk states "most intriguing was the marked effect of neurofeedback on executive functioning... about a 60% increase... to my knowledge no other treatment has achieved such marked improvement in executive functioning, which predicts how well a person will function in relationships, in school performance, and at work" (p. 330). Several neurofeedback studies involve follow up data and have found evidence that symptoms continue to improve for weeks or months post treatment. Rance et al. (2018) found these gains post treatment in two distinct data sets and postulated that brain learning in neurofeedback may instigate a process of learning consolidation and reconsolidation over time resulting in continued brain function enhancement even once sessions have stopped. Such studies inspire curiosity about how different neurofeedback methods may be used to invoke potent and lasting neuroplastic changes in the brain, particularly in the PFC region.

Other naturalistic studies looking at neurofeedback in the treatment of mental health conditions suggest that it can be an effective intervention across diagnostic groups. Cheon et al. (2015) applied EEG-based neurofeedback to 77 clients in a naturalistic outpatient setting and reported significant changes between pretreatment and posttreatment (after a mean of 17 neurofeedback sessions) in clinician rated global clinical improvement scores and self-rated scales measuring symptoms of depression, anxiety, and inattention. Fleischman (2022) reported on the clinical impact of applying infra low frequency neurofeedback to complex psychiatric presentations in an underserved mental health population. Fleishman

reported reductions in drug/alcohol relapse and use of ER/Hospital after 20 neurofeedback sessions. Clients showed improvements in a cognitive test of attention and impulse control as well as positive changes in how well they perceived themselves coping with stress.

The current study seeks to expand our understanding of the application of neurofeedback in mental health. Its intention is to examine the possible advantage of integrating neurofeedback into treatment across diagnoses. It also assesses whether a neurofeedback system (pIR HEG) that is particularly easy to implement can produce substantial findings. If a very simple system can be used to treat underlying neurobiological mechanisms successfully, this calls even more profoundly for an examination of the use of neurofeedback and other psychophysiological approaches within the context of mental health primary care.

Hemoencephalography (HEG) is a type of non-invasive neurofeedback technology invented in 1994. Hershel Toomim developed HEG technology as a poor man's MRI. When a region of the brain is used, cellular metabolism can be detected through changes in cerebral blood flow. Rather than measuring brain activity through the traditional methods involving EEG brain waves, HEG detects brain activity through changes in cerebral blood flow in the PFC. Toomim invented the Near Infrared HEG system [see Kohl et al. (2020) for a review on studies evaluating fNIRS]. In Toomim's design, increasing blood oxygen levels are detected and shown to the client as the PFC is exercised. Carmen invented a similar system also in 1998. Carmen's Passive Infrared Hemoencephalography (pIR HEG) system measures heat distally without skin contact. The pIR HEG system detects increases in thermal waste in the PFC, produced as a by-product of cellular metabolism. Both types of HEG systems use simple headbands that allow for direct training of the PFC.

Both Toomim and Carmen (2009) addressed the focus on prefrontal training. Toomim noted that by examining literature on brain imaging, the source of most aberrant behavior can be linked to hypoperfusion in the frontal lobes. Carmen posited that through the enhanced activation of the prefrontal cortex, there is a helpful inhibition on the rest of the brain resulting in diminished expression of migraines and other brain events. Although systems were applied to various specific brain-related disorders, the impact on global brain control and self-regulation was noted by both developers.

The pIR HEG sensor sits at the Fpz brain training location and measures a relatively large area directly in the center of the forehead. Studies have demonstrated that pIR HEG shows a reduction of thermal variability in the prefrontal cortex (Carmen, 2004; Coben et al., 2008). As a result, Carmen states that pIR HEG can be useful across diagnoses and can result in reductions in the rate and magnitude of behavioral responses. Despite the theorized impact on self-regulation, there are no published studies on pIR HEG applied to mental health conditions. The literature shows that it has been successfully and safely applied to clients for the treatment of migraines (Carmen, 2004; Stokes & Lappin, 2010; Walker & Lyle, 2016).

Scientist- practitioner approach to this clinical pilot study

In applying pIR HEG to the clinical mental health population, the principal investigator adopted a scientist-practitioner approach. 1400 pIR HEG sessions were implemented with 100 clients. As this first contingent received treatment, quotes were recorded that captured changes from their point of view. For a more formal evaluation of the clinical program, clients were asked to complete the same questionnaires before starting pIR HEG (baseline), after 5 sessions, after 10 sessions, and after 15 sessions. Even after questionnaires were introduced, clients continued to share their own view of stressors in their lives and observations of their own behavioral responses to them. Clients self-reported observations are organized into 4 types. See Tables 1-4 for a collection of direct quotes and observations by the first 100 clients.

Table 1

A collection of clients' direct quotes related to "quieting the nervous system"

- "I am more present"
- "I feel better on the inside"
- "I am having fewer panic attacks and I can think my way through them. Something is different"
- "I had a conflict with my landlord and I waited two days to respond"
- "I used to yell and scream. I can see the things I used to react to. I used to feel like I had to say it and now I don't have to say it"
- "Before neurofeedback I used to feel a lot of dread. My hopelessness is much better. I don't feel dark and depressive anymore"
- "My over-reactivity is not controlling me anymore"
- "It feels like I can figure out stuff instead of freaking out"

Table 2

A collection of clients' direct quotes related to "Window of tolerance expanding"

- "I feel more irritated rather than shut down"
- "I feel more anger than panic/hopelessness"
- "I am able to allow myself to be sad"
- "I have been tearful and experiencing more emotion, not just anger/ anxiety"
- "I realize my feelings are normal. I have less doubt about being crazy"
- "Sadness, anger, disappointment, and grief are coming up. These are things I can't change and I don't have to"
- "I am feeling and I can tolerate the feelings. I am not numbing out"

Table 3

A collection of clients' direct quotes related to "self-agency"

- ⦿ “It feels like I am on the ball”
- ⦿ “My focus has shifted to me”
- ⦿ “I said yes to something uncomfortable that led to a promotion at my job”
- ⦿ “There is more of a sense of I can handle this”
- ⦿ “I asked my boss to work from home 1 day per week”
- ⦿ “I feel like I am standing up for myself”
- ⦿ “My daughter got COVID and I didn’t worry. I can tackle this. I am doing the best I can”
- ⦿ “I have more authority over what I want”

Table 4

A collection of clients’ direct quotes related to “self-observation/ awareness”

- ⦿ “I was aware of my heightened state. I notice anxiety in my body when I lie down at night. It feels like an activating sensation in my chest”
- ⦿ “I am more open to suggestions. I realize that many of the fights with my parents and my boyfriend are my fault”
- ⦿ “This has made a huge difference coming here. My awareness of myself has increased. Noticing my own experience of working at my job, asking myself ‘Why am I working here?’”
- ⦿ “I realize that I am afraid of going back to pretending that I am okay and I don’t want to do that”
- ⦿ “It is amazing that I had anxiety the other day and my mind went to ‘isn’t that interesting?’- this is not the usual way I would relate to my anxiety”

The above observations led to a test construction process. In noting the types of positive changes reported by clients, items were created that described the opposite. For example, items were constructed to capture a sense of “feeling stuck” and “feeling helpless” as the opposite of self-agency. Items were created to capture “feeling on edge”, “anxiety in my body,” “overreacting emotionally,” as the opposite of a quieted nervous system. The total scale includes 17 items created to comprise the Limbic Overload© scale. This scale is meant to be a measure of the perception of one’s mental state when there is a general lack of brain control over emotions and deficits in self-regulation. After the scale was completed by 92 total clients, Cronbach’s Alpha was calculated to be .91-.93 showing high internal consistency for the scale.

Table 5

Limbic Overload© (Tyrrell Baker, 2020)- 17 items are rated on a 10-pt scale from 0=Never to 10=All the time. Item scores were summed to create a total score. Please contact author for use of this scale.

1. I have trouble controlling my anger/ irritability.
2. I feel stuck, unable to change.
3. I feel panicky and anxious in my body.
4. I feel helpless.
5. I feel on edge/ hypervigilant.

6. I am scattered in my mind and can't focus.
7. I find myself overreacting emotionally.
8. I procrastinate.
9. I numb, distract, and/or avoid things.
10. I ruminate about my problems.
11. I can't make decisions.
12. I am stressed.
13. I feel like hiding rather than reaching out.
14. I am overwhelmed.
15. I am tired in my body.
16. I have symptoms of digestive problems.
17. I have pain in my body.

Purpose of the study

This program evaluation study examined the effectiveness of pIR HEG neurofeedback across common clinical diagnoses in outpatient mental health private practice. The goal was to determine whether clients receiving pIR HEG sessions showed significant improvement on quantitative measures collected after every 5 sessions of neurofeedback.

1. Is there a statistically significant difference between individuals' baseline depression, anxiety, limbic overload, and self-efficacy scores and their scores after 5 sessions, 10 sessions, and 15 sessions of pIR HEG neurofeedback?
2. For significant differences, what are the estimated effect sizes for these measures across clinical diagnoses? How many sessions result in a change? Are those changes maintained? Are there additional gains with additional sessions?

It was anticipated that clients would show significant decreases in anxiety, depression, limbic overload, and increases in self-efficacy. Hypotheses were based on the prefrontal cortex's inhibitory power as well as qualitative reports from clients.

Method

This within-subjects research design occurred in a private practice setting treating adults presenting with issues related to anxiety, depression, stress, and trauma. The purpose of the data collection was to be able to evaluate the efficacy of the implementation of pIR HEG into the principal investigator's clinical practice. Prior to completing baseline questionnaires, clients were oriented to the fact that the investigator was using the data to assess the impact of pIR HEG on mental health outcomes and to document those findings. Clients were informed that questionnaire data would be used to track individual progress. With as much transparency as possible, clients were presented with pre-post graphs of the changes in their measures as part of the clinical treatment process. Clients were not required to attend a particular number of pIR HEG sessions. Data was collected through a rolling process where each person completes questionnaires at baseline, after 5, after 10, after 15, and continuing every 5 sessions while in treatment.

For the purpose of this investigation, group data is reported on 66 clients who completed baseline and after 5 session measures. In addition, data is reported on 46 of the 66 clients who completed baseline and after 10 measurements, as well as data on 21 of the 66 clients who completed baseline and after 15 measurements.

Participants:

The present study included data from a total of 66 clients ranging in age from 19-66. There were 20 males and 46 females in this predominately white middle class sample in Upstate NY. Clients' diagnoses included Generalized Anxiety Disorder, PTSD, Persistent Depressive Disorder, Major Depression, ADHD, Bipolar Disorder, Adjustment Disorder, and Panic Disorder. 28 of the 66 total individuals presented with PTSD or trauma-related issues as their primary problem. Baseline measurements revealed that this sample population presented with a mix of anxiety and depression. For depression scores (PHQ-9), 38% fell into the mild range, 23% in the moderate range, and 39% in the severe range. For anxiety scores (GAD-7), 32% of clients report none-minimal anxiety, 29% reported moderate anxiety, and 39% reported severe anxiety. Both of these measures were originally designed to screen for anxiety and depression in primary care settings. Given that this is a clinical population presenting with distress and many with trauma histories, scores skewed to the more severe side are expected.

Measures

Patient Health Questionnaire-9. (PHQ) (Kroenke et al, 2001). The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring, and measuring the severity of depression. The PHQ-9 incorporates DSM-IV depression diagnostic criteria with other leading major depressive symptoms into a brief self-report tool. The PHQ-9 asks clients to rate their level of each symptom over the last two weeks as "0" (not at all) to "3" (nearly every day). PHQ-9 scores of 5, 10 and 15 represent mild, moderate, and severe depression, respectively.

Generalized Anxiety Disorder Assessment-7. (GAD) (Spitzer et al, 2006). The Generalized Anxiety Disorder Assessment (GAD-7) is a brief measure for symptoms of anxiety, based on the generalized anxiety disorder diagnostic criteria described in the Diagnostic and Statistical Manual of Mental Disorders (DSM). The GAD-7 assessment asks clients to evaluate their level of symptoms over the last two weeks. A symptom severity description is presented based upon the raw score: 0-4 = None-Minimal; 5-9 = Mild; 10-14 = Moderate; 15+ = Severe.

Limbic Overload(LO). (Tyrrell Baker, 2020)

This scale was developed by the author of this study through a test construction process based on clients' reports of where they felt stuck and areas of stress perception that improved with pIR HEG sessions. The scale includes items endorsed by clients who report the feeling of mental and physical overwhelm. The scale has 17 questions including three types of experiences: 1) general feelings of being stressed, overwhelmed, and stuck; 2) feelings of being on edge, hypervigilant, scattered, and anxious in the body; 3) feelings of being numb, avoidant, tired, and in pain. Each item is rated on a 10-point scale from "Never" to "All the time." Scores on the

17 items were summed to come up with a LO total score. Cronbach's Alpha was calculated to be .91-.93 showing high internal consistency for the scale.

Global Self Efficacy (GSE). (Schwarzer & Jerusalem, 1995)

The General Self-Efficacy Scale is a 10-item psychometric scale that is designed to assess optimistic self-beliefs to cope with a variety of difficult demands in life.

The scale was developed in German by Matthias Jerusalem and Ralf Schwarzer in 1981 and has been used in many studies with thousands of participants. In contrast to other scales that were designed to assess optimism, this one explicitly refers to personal agency, i.e., the belief that one's actions are responsible for successful outcomes. Each of the 10 items are rated on a 4-point scale: 1 = Not at all true 2 = Hardly true 3 = Moderately true 4 = Exactly true. The sum is the GSE score, ranging between 10 and 40. Internal reliability for GSE = Cronbach's alphas between .76 and .90 The General Self-Efficacy Scale is correlated to emotion, optimism, work satisfaction. Negative coefficients have been found for depression, stress, health complaints, burnout, and anxiety.

Coping Self efficacy (CSE). (Chesney et al, 2006).

The CSE scale provides a measure of a person's perceived ability to cope effectively with life challenges. This measure focuses on changes in a person's confidence in his or her ability to cope effectively which, according to self-efficacy theory (Bandura, 1997), is an important prerequisite to changing coping behavior. CSE was assessed with a 26-item measure of perceived self-efficacy for coping with challenges and threats. Participants were asked, "When things aren't going well for you, or when you're having problems, how confident or certain are you that you can do the following..." They were then asked to rate on an 11-point scale the extent to which they believe they could perform behaviors important to adaptive coping, such as 'sort out what can be changed, and what cannot be changed', 'break an upsetting problem down into smaller parts', 'look for something good in a negative situation', and 'get emotional support from friends and family'. Anchor points on the scale were 0 ('cannot do at all'), 5 ('moderately certain can do') and 10 ('certain can do'). Scores range from 0-260.

Brief Dissociative Experiences Scale (DES-B). (Dalenberg & Carlson, 2010) This is an 8-item measure that assesses the severity of dissociative experiences in individuals ages 18 and older. Each item asks the individual receiving care to rate the severity of his or her dissociative experiences during the past 7 days. Each item on the measure is rated on a 5-point scale (0=Not at all; 1=Once or twice; 2=Almost every day; 3=About once a day, and 4=More than once a day). The total score can range from 0 to 32, with higher scores indicating greater severity of dissociative experiences. The total scores were used as data in this investigation.

Data Collection Procedures

Clients were asked to complete questionnaires at baseline, after 5 sessions of neurofeedback, after 10 sessions, and after 15 sessions. Questionnaires were completed electronically as part of clients' ongoing treatment in the principal investigator's private practice. This section describes procedures for the pIR HEG neurofeedback training process.

Jeff Carmen's EZ pIR neurofeedback system was used for all clients. The system uses a headband with two infrared sensors capturing thermal activity from the center of the forehead. It captures infrared radiation within the 7-to-14-micron band, with field of view of 1.5 in X 2.0 in. The sensor assembly records infrared light waves emitted from the forehead in much the same way that a camera records visible light waves reflected from objects. The sensor assembly has a response time of 80 milliseconds. The data sampling rate is 30 times per second. (Carmen, 2018)

The EZ pIR protocol uses a DVD of a Hollywood film as an emotional stimulus. Clients pick from a small collection of movies in the clinician's office and are instructed to choose a movie that "resonates" with them, a movie that they find satisfying to watch. Clients were generally instructed to avoid films that are upsetting to them and films that they have seen multiple times where they can anticipate each scene. Most often clients would choose a DVD that would be used from session to session, starting wherever they left off in the prior session. Clients were able to change the movie for the next session anytime they wanted.

When the sensors on the forehead detect a decrease in thermal output in the PFC, the movie freezes and a bar graph appears on the screen. The bar graph shows whether heat coming off the PFC is rising or falling. The client then uses the information in the bar graph to voluntarily exercise the PFC, learning to return heat to this part of the brain, thereby prompting the movie to play again. In any given session, clients obtain approximately 10 minutes of active brain exercise over a total of approximately 30 minutes.

The principal investigator served as the clinician for all neurofeedback sessions. She received direct training from Jeffrey Carmen, PhD. There are very few complications to the implementation process- the way the equipment is used takes seconds to set up (put on headband and give basic instructions) and is the same for each client. The only assumption is that regardless of primary diagnosis, greater PFC activation and connectivity is the goal.

Although no side effects were reported, clients were monitored for frontal fatigue. In order to make sure pIR HEG sessions were implemented safely, a maximum of 10 minutes of active training time (time when movie is paused and person is exerting effort) was allowed for each neurofeedback session. Generally, the time spent in the neurofeedback training session was between 23-30 minutes, an approximate ratio of 1:3 active training time to overall elapsed time. In addition, sessions were spread apart by at least one week. The neurofeedback session was stopped if the patient reported any headache or forehead discomfort. Needing to stop the session early was not necessary in most cases with clients gaining 10 minutes of active prefrontal training during each session.

Results

Scores on anxiety (GAD-7) and depression (PHQ-9) at baseline and after 5, 10, and 15 sessions of neurofeedback were organized into categories of symptom severity. Table 6 shows the

number (and percentage) of clients reporting minimal/mild, moderate, and severe levels of symptoms.

A series of paired one-tailed t-tests were conducted to compare data collected after 5 sessions, after 10 sessions, and after 15 sessions with data collected from the same clients at baseline (before neurofeedback sessions began). After 5 sessions, measures of anxiety, depression, limbic overload, and coping self-efficacy showed statistically significant changes.

After 10 sessions and after 15 sessions, t-tests showed statistically significant changes in mean scores across all measures. While depression, anxiety, limbic overload, and dissociation decreased, general self-efficacy and coping self-efficacy increased. See Table 7 for t-test results as compared to clients' baseline measurements. Because the measure of dissociation was added after other measures, t-tests on the DES-B are reported separately in Table 10.

Data was analyzed using a series of paired one-tailed t-tests to see if clients benefitted from additional sessions. Table 8 reveals results comparing patient scores after 5 sessions with their scores after 10 sessions. Table 9 shows results of comparing patient scores after 10 sessions with their scores after 15 sessions. All measures show additional statistically significant changes in client scores between 5 and 10 sessions. Between 10 and 15 sessions, all measures showed statistically significant changes except anxiety which essentially stayed stable between 10 and 15 sessions. Effect sizes were calculated for any statistically significant results. Hedges g was used to compute effect sizes via the following link:

<https://effectsizecalculator.herokuapp.com/#paired-samples-t-test>. See Tables 7-10 for estimated effect sizes.

Table 6

Number of clients reporting symptoms in the minimal, moderate, and severe ranges of anxiety and depression

	Score on PHQ	Baseline	after 5 neurofeedback sessions	after 10 neurofeedback sessions	after 15 neurofeedback sessions
Depression	Mild 0-9	25 (38%)	46 (70%)	37 (80%)	21 (100%)
	Moderate 10-14	15 (23%)	13 (20%)	6 (13%)	0
	Severe 15-27	26 (39%)	7 (10%)	3 (7%)	0
	Total subjects	66	66	46	21
Anxiety	Score on GAD-7	Baseline	after 5	after 10	after 15
	Mild 0-9	21 (32%)	38 (58%)	36 (79%)	19 (90%)
	Moderate 10-14	19 (29%)	18 (27%)	8 (17%)	2 (10%)
	Severe 15-21	26 (39%)	10 (15%)	2 (4%)	0
	Total subjects	66	66	46	21

Table 7 Paired one-way t-test analyses comparing the same clients at baseline to the same clients after 5, 10, and 15 sessions of pIR HEG.

	Baseline	After 5 sessions	Effect size	After 10 sessions	Effect size	After 15 sessions	Effect size
PHQ	12.09	8.299***	g= .60	5.935***	g=.96	3.619***	g=1.4
GAD	12.104	8.672**	g=.60	6.109***	g=1.1	4.571*	g=1.1
GSE	29.03	30.463	N/A	32.739**	g=-.71	33.524*	g=-1.0
CSE	118.015	145.149***	g=-.58	169.043***	g=-1.05	187.286**	g=-1.4
LO	113.418	90.567***	g=.76	77.652***	g=1.34	64.524***	g=1.55
sample	n=66	n=66		n=46		n=21	

Statistical significance associated with t-tests ***p<.001, **p<.01, *p<.05

Table 8

Paired one way T-tests comparing post 5 sessions to post 10 sessions (n=46)

	After 5 sessions	After 10 sessions	Effect size
PHQ	7.61	5.93**	g=.33
GAD	8.2	6.12**	g=.42
GSE	30.85	32.74***	g=-.46
CSE	148.96	169.04***	g=-.41
LO	87.43	77.65**	g=.35

Statistical significance associated with t-tests ***p<.001, **p<.01, *p<.05

Table 9

Paired one way T-tests comparing post 10 sessions to post 15 sessions (n=21)

	After 10 sessions	After 15 sessions	Effect size
PHQ	5.38	3.62**	g=.45
GAD	4.81	4.57	N/A
GSE	32.05	33.52*	g=-.39
CSE	171.95	187.29**	g=-.34
LO	73.57	64.52*	g=.32

Statistical significance associated with t-tests ***p<.001, **p<.01, *p<.05

Table 10

Dissociative Experiences Scale- Brief (DES-B) results

	Baseline	After 5 sessions	Effect size	After 10 sessions	Effect size	After 15 sessions	Effect size
DES-B	10.0	9.0	N/A	7.41**	g=.59	5.73**	g=.49

Sample n=48 n=22 n=15

Statistical significance associated with t-tests ***p<.001, **p<.01, *p<.05

Discussion

This study demonstrates the possible advantages of integrating non-invasive prefrontal neurofeedback into the treatment of common mental health conditions. In particular, we examined the application of pIR HEG neurofeedback which has shown positive results for the safe and effective treatment of migraines but has not been formally examined in the treatment of mental health. HEG neurofeedback approaches have the dual advantage of being easily implemented in a traditional mental health office setting as well as allowing direct training of the prefrontal cortex.

The current study showed significant changes in anxiety, depression, general self-efficacy, limbic overload, and coping self-efficacy after 5 sessions of pIR HEG when compared to baseline. The changes after 5 sessions yielded moderately large effect sizes (g=.58-.76) and these positive changes were both maintained and enhanced with additional sessions. Effect sizes for within group analyses increased when comparing scores after 10 sessions and after 15 sessions with all outcome measures showing very large effect sizes (g=.71-1.55).

Limbic Overload (Tyrrell Baker, 2020) was created using a test construction process based on previous qualitative report from 100 clients regarding the changes they perceived as a result of pIR HEG neurofeedback. This scale was validated in the present study in terms of the pattern of scores following that of anxiety and depression scores generally. Clients reported feeling less stuck, avoidant, and less overwhelmed as their neurofeedback sessions increased, consistent with early qualitative reports from clients.

DES-B was used to assess the impact of this non-invasive brain training on dissociative experiences. Scores decreased from a mean of 10 at baseline to a mean of 5 at 15 sessions. Clients reported fewer aberrant experiences of depersonalization and derealization after receiving neurofeedback. This also provides converging evidence of clients' qualitative reports in terms of feeling present, less reactive, and more emotionally tolerant.

The results of the current study provide some initial evidence that the impact of pIR HEG sessions on mental health outcomes is noteworthy in a few different ways. One is the robustness of clinical changes reported. The range in anxiety and depression scores reveal the scope of these changes. At baseline, 62% of our sample reported moderate or severe depression on the PHQ. After 15 sessions, 100% of clients reported depression in the mild or minimal range. A similar robust pattern was observed in anxiety. At baseline, 61% of our sample reported anxiety in the moderate or severe range on the GAD-7. After 15 sessions, 90% of clients reported that their symptoms had fallen into the minimal to mild range of anxiety.

Findings in the realm of self-efficacy are also worth noting. Both global self-efficacy (after 10 sessions and after 15 sessions) and coping self-efficacy (after 5, 10, and 15 sessions) showed significant increases. Self-efficacy is an important predictor of function in many domains. In Bandura's theory of self-efficacy, performance accomplishments are the most potent contributor to one's overall self-efficacy (Bandura, 1997). According to the theory, in the realm of coping and healthcare, somatic indicators (or what is perceived in the body) is also a significant contributor. The increases in global and coping self-efficacy seen in this study make sense in the context of neurofeedback influencing the experience of somatic indicators of safety and tolerance rather than fear and overwhelm. Even more significant is what happens when people rapidly develop coping self-efficacy. Having higher self-efficacy results in people approaching tasks that they would generally avoid or give up on. By approaching coping tasks and persisting, clients rapidly build coping accomplishments in a way they have generally not experienced before. In addition, after experiencing some success and feelings of capability, clients are more open to reflect on times where their coping is challenged. From this perspective, an intriguing aspect of neurofeedback in mental health is the possibility of creating a snowball effect with somatic changes, emotional tolerance, self-efficacy, and reflective learning enabling a new level of personal agency, coping, and health over the longer term (Tyrrell Baker, 2022)

Limitations

Although multiple measurements over time in this study present a design advantage, conclusions based on the current study are limited by the pre-post within-subjects design. Without random assignment and control groups, we cannot conclude that the pIR HEG neurofeedback is responsible for the effects we have demonstrated here. In addition, it is possible that the clinician's attention to "change" through graphing changes in questionnaire measurements and discussing them with clients led to some of the robustness of these changes. Data-driven practice could affect outcomes through the clinician's active attention and interest in the possibility of change. If sharing continuous data with clients contributes to the robustness of the neurofeedback effects, it could be adopted by neurofeedback practitioners both to enhance care and provide validation of the method being used. We need well-designed larger scale studies on EEG and HEG neurofeedback as applied to mental health populations. In the meantime, given the number of systems being used, it makes ethical and practical sense to integrate a data-driven approach to continuously evaluate and validate the impact of neurofeedback on mental health.

In this naturalistic study, because we included people both with PTSD, without PTSD, with a trauma-focused reason for seeking care, and those seeking care for other reasons, we cannot make conclusions if results would vary in some way if these groups were looked at separately.

In addition, the present study does not look at any follow up data. Even though it appears that 5 sessions of pIR HEG can be potent and 10 or 15 sessions even more potent, it does not assess the longevity of the effects over time.

By suggesting that a simple system like pIR HEG can have a relatively fast and powerful impact on the treatment of mental health, it would be easy to conclude that the myriad of guided meditation apps or at-home brain training devices could result in such significant changes. Although individuals may gain significant relief with self-treatment, at home treatment suffers from lack of consistency and implementation standards. Harnessing new implicit skills that come online as a result of neurofeedback can be significantly enhanced by a knowledgeable clinician. Skilled clinicians help clients interpret changes and develop a new way of observing themselves and their coping responses. Clinicians can observe on how brain changes manifest in thinking and behavior and help clients to connect the dots. Without helpful observation and guidance, clients are likely to ignore aspects of their behavior that are inconsistent with their familiar habits or historical self-beliefs (Bandura, 1997; Dana, 2018).

In summary, studies like this one do not fill the need for well-designed research studies on neurofeedback and mental health. On the other hand, such qualitative and quantitative reports can provide a clear ethical and scientific motivation to engage in further study. Through the targeted use of neuroscience technology, we may be able to consistently improve executive function across diagnoses in an effective and efficient manner. In fact, given the ease of implementation in an office setting and no side effects, the pIR HEG tool is a low-risk medical

device which can teach us that we can easily target psychophysiological aspects of mental health and, when we do, treatment might be able to take a new course. In meeting the ever-increasing mental health needs of our human population, efficient and effective approaches are critical. The current study demonstrates that neurofeedback and other neuroscience informed learning technologies may be able to help providers design shorter term models that actually address underlying psychophysiology, build implicit skills, and instigate strong shifts in self-efficacy needed to live well in an ever changing, stressful world.

Disclosures

Author has no grant support, financial interest, or conflicts to disclose.

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