BRAINFUTURES

Neurofeedback

An Efficacious Treatment for Behavioral Health

Summary of the Evidence

What the Research Shows

Behavioral health issues among youth are on the rise. Attention-deficit and hyperactivity disorder (ADHD) and anxiety-related conditions are particularly ubiquitous. More than 10% of U.S. children and teens are currently diagnosed with ADHD (Children and Adults with Attention-Deficit/Hyperactivity Disorder, 2020) and 25% of children experience some form of anxiety (Centers for Disease Control and Prevention [CDC], 2018a). Neurofeedback (NFB) is a compelling non-invasive treatment for these conditions—and it deserves more attention from patients, providers and payers. The intervention uses non-invasive sensors and a digital interface to measure brainwaves, allowing individuals to observe and modulate their own brain's activity. The following summary of evidence is excerpted from BrainFutures' 2020 report, Neurofeedback: An Efficacious Treatment for Behavioral Health. It reviews the evidence base for NFB as a first-line treatment for ADHD and as an effective treatment for anxiety.

NFB IS EFFICACIOUS AND SPECIFIC IN TREATING ADHD

Research over the past 20 years has significantly built on the pioneering NFB studies of the 1970s, '80s, and '90s. New studies, reviews and meta-analyses have investigated the efficacy and effectiveness of NFB under a variety of standard protocols, populations and conditions. The take away from this review of evidence is that NFB should be a first-line treatment with certain conditions. Even the vast majority of sham studies—designed to test whether the outcomes of a treatment are valid or little more than placebo effect—showed that NFB does have an effect greater than placebo when properly applied. (See Sham or the Real Deal in the full NFB report for more information.) Following are summary research findings that support NFB as an effective treatment for ADHD and other conditions.

NFB should be [a] first line of treatment for ADHD.

In a 2014 review, psychologist H. Edmund Pigott and neuroscientist Rex Cannon state that NFB should be the first line of treatment for ADHD. In their review, they point out that while upwards of 70% of children diagnosed with ADHD are prescribed amphetamine medication, medication as a treatment fails to result in sustained benefits for most children. They indicate challenges with comorbid symptoms such as anxiety, depression, and learning disorders, that can lead to misdiagnosis, and therefore recommend NFB be used first in the case of ADHD treatment, as it is efficacious, non-harming, and non-pharmacological (Pigott et al., 2014).

Beyond comparison to medication, NFB was found to be more than twice as effective as the other interventions, which included behavior modification, multimodal psychosocial treatment, school-based programs, working memory training, parent training, and self-monitoring, in a 2014 meta-analysis that reviewed outcomes from 14 controlled studies including 625 subjects (Hodgson et al. 2014). The review focused on NFB as a treatment for ADHD relative to the effectiveness of other evidence-based non-pharmacological treatments.

Similarly, another 2014 study—that randomly assigned 104 grade-school children from public schools diagnosed with ADHD to treatment with NFB, cognitive training (CT), or nothing (control)—found significant improvements with NFB treatment (Steiner et al., 2014). After 6 months of interventions, the NFB groups showed a strong reduction in ADHD symptoms indicated by increases in attention and executive function compared to the other two groups. In addition, of the children in the study who were already

taking methylphenidate, the medication dose levels for the CT and control groups increased significantly over time based on symptoms in order to maintain outcomes, while the NFB group had no significant dosage increase. Overall, the study found significant improvements for the NFB group in children who were both on or off medication. This research supports NFB as both a stand-alone and adjunct treatment for ADHD.

The research continues to validate the effectiveness of NFB as a treatment across study designs and measures. For example, a 2014 meta-analysis of randomized control trials (RCTs) that summarized research including 263 children (146 using NFB and 117 in active control or sham control groups) found that NFB significantly improved inattentiveness, impulsivity and hyperactivity according to parent assessments. (Micoulaud-Franchi et al., 2014). Significant improvements in inattentiveness were also reported through teacher assessments.

Meanwhile, large-scale reviews have indicated across research that NFB hits high marks when it comes to efficacy of treatment for ADHD. According to a 2009 meta-analysis that included 1,194 subjects from 10 controlled studies, NFB is efficacious and specific (classified as Level 5, meaning statistically superior to sham or alternative treatment) for ADHD (Arns et al., 2009). In the research reviewed, NFB was found to be most effective at treating inattention and impulsivity aspects of ADHD.

To further support NFB as a first-line treatment, a 2012 study concluded that NFB yields similar initial outcomes to medication (Duric et al., 2012). This RCT included 91 children aged 6- to 18-years-old and investigated treating ADHD with either NFB or methylphenidate. Improvements were measured as changes in symptoms reported by parents. Both NFB and medication reported equal improvements during and following treatment: NFB three times a week for a total of 30 sessions, or 1 mg per kg of methylphenidate for the same time period. The study concluded that NFB significantly improved symptoms of ADHD with the same effectiveness as methylphenidate, supporting NFB as a valid primary treatment option for ADHD in children.

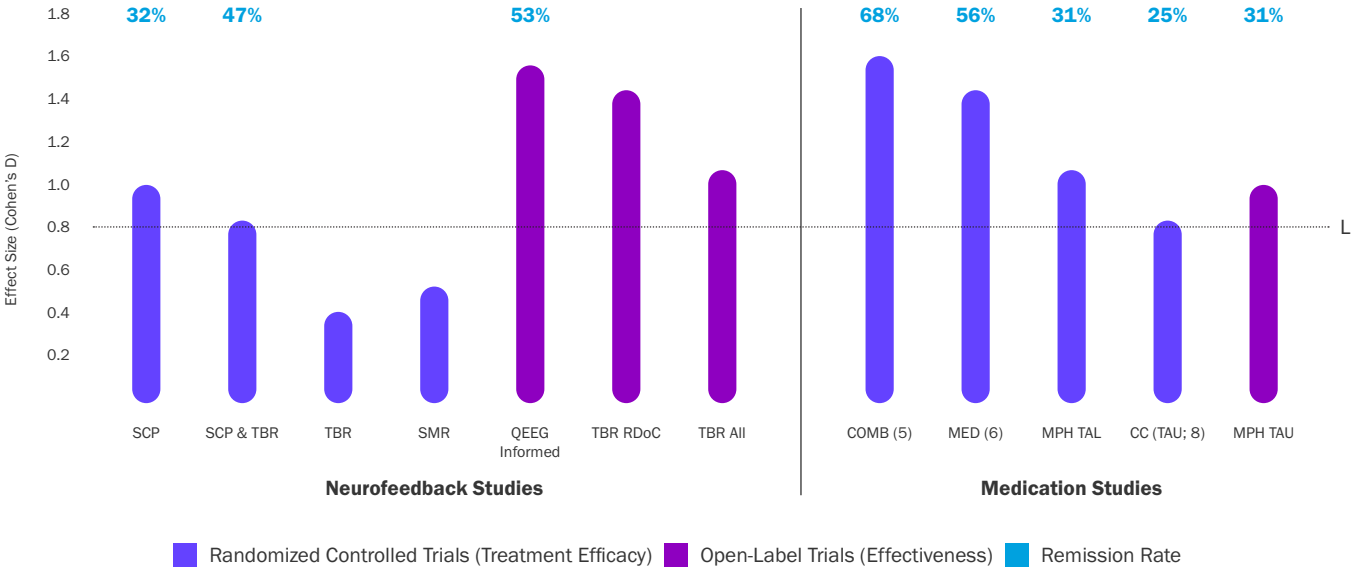
Other studies have found similar initial outcomes and further concluded more successful post-treatment outcomes for NFB. A recent meta-analysis investigated the effects of NFB as a treatment for ADHD compared to medication and found that NFB was "superior on non-active control groups [i.e. open-label] and similarly effective for inattention and hyperactivity/impulsivity compared to active treatments" (Van Doren et al., 2018). Further, this same study noted that the "findings provide evidence that there are sustained clinical benefits after neurofeedback and active treatments over an average 6–12 month follow-up period, whereas effects of non-active control groups are no longer significant at [follow-up]."

A 2019 review of meta-analyses and randomized controlled trials found similar evidence supporting NFB in lieu of medication (Enriquez-Geppert et al., 2019). The study stated: "... in response to the lack of long-term effects for both medication and behavioral therapy and the side effects of medication... we provide evidence for the efficacy and specificity of standard neurofeedback protocols." The study concluded that neurofeedback should be a viable treatment for ADHD, while encouraging continued research to further identify specific protocols.

Very recent research reinforces NFB as an equal treatment to medication as compared to the landmark ADHD medication studies. A 2020 quantitative review evaluated the effectiveness and efficacy of NFB by comparing its research outcomes to the NIMH-MTA studies for medication and behavior therapy (Arns et al, 2020). The review found NFB to be both effective and efficacious as a treatment for ADHD compared to medication and/or therapy, and failed to find any side effects from NFB as a treatment. More importantly, in RCTs, ADHD remission rates following treatment with NFB ranged from 32-47%, on par or better than rates for methylphenidate, behavior therapy, or community care as treatment (see Figure 3A). In addition, in four RCTs, NFB resulted in continued improvement in ADHD symptoms after treatment ended (see Figure 3B). This post-treatment increase in improvements was also true for behavior therapy and community care, but not for medication, which showed a decrease in effectiveness at follow-up, indicating that the benefits of medication are immediate and not lasting.

FIGURE 3A: NFB COMPARED TO METHYLPHENIDATE MEDICATION

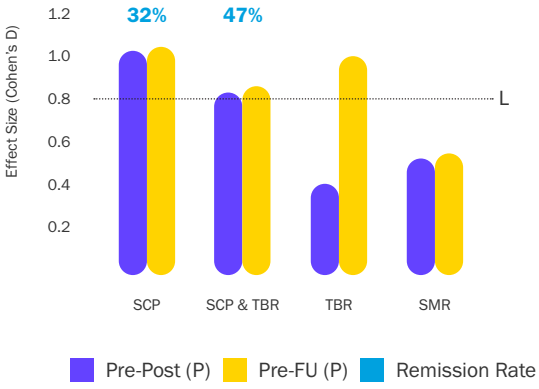
Arns, M., Clark, C. R., Trullinger, M., deBeus, R., Mack, M., & Aniftos, M. (2020). Neurofeedback and Attention-Deficit/Hyperactivity-Disorder (ADHD) in Children: Rating the Evidence and Proposed Guidelines. Applied Psychophysiology and Biofeedback, 45(2), 39–48. https://doi.org/10.1007/s10484-020-09455-2



The above figure compares effect sizes for several independent studies investigating various treatments for ADHD. L signifies a large clinical effect size (>0.8). All neurofeedback studies employed one of the following standard NFB protocols: sensori-motor Rhythm (SMR), theta/beta neurofeedback (TBR), or slow cortical potential (SCP). In the first open-label neurofeedback study a QEEG-informed procedure was used to select the right standard protocol and in the second open-label study, subjects were pre-selected on high TBR (TBR RDoC). The RCT medication outcome measures were from the NIMH Multimodal Treatment Study of Children with ADHD (MTA). The MTA study was composed of four arms: combined treatment of medication and therapy (COMB), medication only (MED), multicomponent behaviour therapy (MBEH), and community care—treatment as usual (CC:TAU). The open label medication study was a multi-centre open-label, treatment as usual (TAU) trial of methylphenidate (MPH) treatment.

FIGURE 3B: NEUROFEEDBACK EFFECT SIZE AT FOLLOW UP

Arns, M., Clark, C. R., Trullinger, M., deBeus, R., Mack, M., & Aniftos, M. (2020). Neurofeedback and Attention-Deficit/Hyperactivity-Disorder (ADHD) in Children: Rating the Evidence and Proposed Guidelines. Applied Psychophysiology and Biofeedback, 45(2), 39–48. https://doi.org/10.1007/s10484-020-09455-2



This figure compares effect sizes of neurofeedback results immediately following treatment (purple bar/Pre-Post Treatment) to follow-up 6 months post treatment (yellow bar/Pre-FU) for several randomized control trials investigating various neurofeedback protocol treatments for ADHD. L signifies a large clinical effect size (>0.8). All neurofeedback studies employed one of or more of the following standard protocols: sensori-motor rhythm (SMR), theta/beta neurofeedback (TBR), or slow cortical potential (SCP).

This is not to disparage medication or to position NFB as a cure-all replacement for medication. There are many behavioral health conditions where the best course of treatment is medication and, in some cases, NFB works well as an adjunct treatment to medication. However, where NFB can be used as a first-line treatment, as with ADHD, there exists the potential benefit of lasting results after treatment ends without side effects or further pharmacological intervention.

The research overviewed above supports both stand-alone NFB and a combination of NFB and medication as potential best practices for treatment of ADHD, underscoring key points that: NFB is as efficacious and effective as medication when used properly; and NFB treatment can result in long-lasting (6-12 months) improvement in symptoms even after treatment has ended, whereas medication typically does not show post-treatment improvements. These findings support NFB as a first-line or adjunct treatment for ADHD.

NFB ELIMINATES AMPHETAMINE-RELATED RISKS

The CDC reports that ADHD affects almost 10 percent of school-aged children, with approximately 3.3 million U.S. children medicated for unfocused behaviors (CDC, 2018b). As such, it is also important to consider the risks and side effects of medicating children with amphetamines, and in some cases additional antipsychotic drugs.

Beyond direct comparison between NFB and medication in terms of effectiveness or efficacy, research indicates that drugs have a higher risk of unfavorable side effects and, in other research, drugs and medication have not been shown to increase academic or life-achievement outcomes (Currie et al., 2014; Loe & Feldman, 2007). Rather, a childhood diagnosis of ADHD is usually followed into adulthood by ongoing treatment and related life challenges. Approximately 40% of treated children continue to experience ADHD as adults, and some engage in drug abuse. Adults that were medicated as children with ADHD are more likely to be antisocial, complete a lower level of education, and hold relatively lower level positions at work, while the ADHD-related attentional and impulsivity challenges from childhood tend to persevere (Mannuzza & Klein, 2000).

[NFB] offers a plausible alternative for children with ADHD whose treatment may be limited by side effects and/or poor medication response.

In a study that evaluated the effects of Ritalin compared to NFB, researchers found, using the Test of Variables of Attention (TOVA) scores, that NFB treatment resulted in sustained improvements. In the same report, they surmised that treatment with stimulants "would appear to constitute a type of prophylactic intervention, reducing or preventing the expression of symptoms without causing an enduring change in the underlying neuropathy of ADHD" (Monastra et al, 2002). These findings should be most importantly understood from the perspective that stimulant medication typically does not produce lasting positive outcomes post-treatment, whereas NFB can. And for some children, especially those with co-occurring disorders, medication may not be the best course of treatment. Researchers have stated that NFB "offers a plausible alternative for children with ADHD whose treatment may be limited by side effect and/or poor medication response" (Vernon et al., 2004).

Similarly, a 2003 study of 34 children compared NFB to methylphenidate. Twenty-two children received 3 months of NFB and 12 took methylphenidate for the same time period. The study found that both NFB and methylphenidate improved attention and reduced ADHD-related behaviors. The research concluded that NFB is a viable treatment for ADHD for parents who prefer a non-pharmacological treatment (Fuchs et al, 2003).

It stands to reason that a treatment option showing equal efficacy at reducing ADHD symptoms and promise for lasting outcomes post-treatment would be welcomed by medical and psychiatric professionals. Further, for some children, responsible and calculated treatment plans could begin with the least potentially harmful treatments—NFB and therapy—and progress towards medication as needed, depending on symptoms and outcomes. In addition, particularly in children, the experience of NFB is often in the form of watching a "movie" or listening to something, which is an enjoyable activity for children and results in higher levels of voluntary patient compliance.

Given recent comprehensive research reviews and current studies there is no reason for NFB to remain largely sidelined by the medical and psychiatric professions. Even though an ADHD diagnosis affects 11% of children aged 4-17-years in the U.S. today, only 11.4% of those diagnosed have ever received EEG NFB (Danielson et al., 2018). More patients, young and old, deserve covered access to and information about this treatment option.

NFB IMPROVES ACADEMIC PERFORMANCE AND ACHIEVEMENT

It is easy to get mired down in the comparative efficacy (and ease of use) of various treatments for ADHD from a reductionist perspective—a viewpoint that if symptoms improve, all interventions are equal relative to the scope of those reduced symptoms. Yet, as mentioned earlier, with ADHD and children, it is important to consider more inputs than just treatment modality and reduction of symptoms in addition to sustained benefits. Beyond proven efficacy as a treatment for ADHD, NFB also improves academic and social outcomes.

Families are understandably seeking solutions that maximize cognitive function, emotion regulation, and life outcomes. More pointedly, one important element, and usually one of the primary reasons why parents seek diagnosis, is to improve their child(ren)'s academic performance; another is to bolster self-reflective and/or self-regulated behavior. It also stands to reason that with improvements in academic performance, self-esteem improves, while school-related oppositional behaviors and test anxiety could be reduced. Without attempting to evaluate the totality of biological, neurological, and environmental inputs that lead to ADHD, which are numerous, for many families a preferred treatment would not only reduce symptoms by creating improvements in inattention, impulsivity and hyperactivity, but also show greater academic and social outcomes. In addition to grades, parents are seeking improvements in their children's quality of life, and in family or peer socialization that may have been obstructed or diminished as a result of ADHD. While the available research shows that NFB is equally as effective as medication alone at treating ADHD, it also shows that NFB is more effective at improving academic and life outcomes.

For example, a 2013 RCT of boys and girls aged 7- to 14-years-old that compared 40 NFB sessions to treatment with methylphenidate also investigated the impact of treatment on academic performance (Meisel et al., 2013). While the research found that both treatments alleviated symptoms of ADHD, at 2- and 6-month follow-ups, only the NFB cohort showed significant improvements in academic performance.

In another study, researchers reviewed data to explore the possible outcomes of treating children with ADHD with medication, not only in terms of improvements in academic performance, but also changes in emotional functioning (Currie et al., 2014). The research used data from the National Longitudinal Survey of Canadian Youth, which include 8,643 participants who were born in 1985 or later. The total longitudinal survey lasted for almost 25 years. The study stated that following increases in the use of prescription medication for ADHD, researchers found "... no evidence that the performance of children with ADHD improved. In fact, the increase in medication use among children with ADHD is associated with increases in the probability of grade repetition, lower math scores, and a deterioration in relationships with parents. When we turn to an examination of long-term outcomes, we find that increases in medication use are associated with increases in the probability that a child has ever suffered from depression and decreases in the probability of post secondary education among girls."

A 2015 review in the Journal of Attention Disorders sought to evaluate the direct impact of all ADHD treatments, or combinations of treatments, on academic outcomes. The researchers looked at 176 studies that measured longer term academic outcomes (at least 2 years) for students with ADHD with and without treatment (Arnold et al., 2015). This research more specifically defined two measures of academic outcomes: 1) academic achievement as information learned, measurable by test scores; and 2) academic performance as overall success in the school environment. Treatment of any kind showed some improvement in both academic achievement and performance. However, multimodal treatment (that combined more than one treatment) had the highest improvement measures in both categories. According

to this study, non-pharmacological interventions performed better at increasing academic performance than pharmacological interventions.

Again, research indicates that while pharmacological interventions may be the simplest and most direct treatment modality to immediately relieve symptoms of ADHD, they are not always the most effective for long-term improvements post-treatment or for improving other outcomes including academic performance and prosocial behaviors. Conversely, non-pharmacological treatments, namely NFB, have been found to result in longer-term post-treatment improvements and increases in academic performance and well-being.

In addition to NFB as treatment for a single child with ADHD as prescribed or directed by doctors or psychologists, as referenced earlier, there exists potential for school-based group NFB interventions for children with ADHD that could improve not only symptoms but also academic and social outcomes. A 2011 study found that computer-based NFB interventions in school successfully reduced symptoms of ADHD (Steiner et al., 2011). The study found improvements through objective measures including the Conners' Rating Scales-Revised (CRS-R), Behavior Assessment Scales for Children (BASC) and the Behavioral Rating Inventory of Executive Functioning (BRIEF).

A 2014 follow-up study by the same researchers found that "participants on medication presented at baseline with the same level of ADHD impairment as those who were not taking medications" (Steiner et al, 2014). Further, they found that because "children on stimulant medication improved to the same magnitude as those not on stimulant medication suggests that stimulant medication does not hamper the therapeutic effect of [neurofeedback] NF. This is clinically an important factor regarding NF attention training and has been debated in previous works, and it means that NF is accessible as a stand-alone therapy option or an adjunctive treatment to medication."

RESEARCH SHOWS NFB ALLEVIATES ANXIETY RELATED SYMPTOMS

As reported in the full NFB report, in addition to being an effective treatment for ADHD, research has shown NFB to be effective for other conditions and symptoms. The words anxiety, stress, and trauma represent different conditions and symptoms, depending on context. Symptoms and experiences of anxiety are common across many behavioral health issues in addition to ADHD, including PTSD, depression, general anxiety disorder (GAD), and a more inclusive general category of stress- and adjustment-related disorders. This latter category could be caused by disruptive life events such as major challenges at work, in health, relationships, or due to accident or injury, both acute and chronic, that manifest symptoms of anxiety, depression and other experiences and emotions without necessarily indicating diagnosis of those conditions per se. As previously noted in the full NFB report, almost 20% of Americans are experiencing some form of anxiety, not to mention the high rates of depression (NIMH, 2019) and stress-related illnesses in the U.S.

When considering NFB as an effective treatment option for these conditions, it is important to remember the original outcomes of NFB, going back to the 1950s and 1960s and the work of Dr. Joe Kamiya. These outcomes were increased relaxation effects shown through voluntary, feedback-assisted modulation of specific brainwaves, namely alpha waves. In other words, NFB got its start in the behavioral health field by inducing "relaxation" as an antidote to stress, anxiety, depression, addiction, and so forth.

NFB can be successful at supporting well-being relative to depression, PTSD, trauma, and adjustment disorders.

Growth in NFB technology since the 1960s, along with discoveries in neuroscience, have resulted in greater understanding of relevant brainwaves, along with increased protocol specificity for producing relaxation outcomes. These relaxation outcomes have transferable impact, namely relieving symptoms of anxiety related

to other disorders. Interestingly, NFB can be successful at supporting well-being relative to depression, PTSD, trauma, and adjustment disorders in an objective way and without necessarily having to explore the underlying contextual or traumatic experience as might occur in therapy. As such, the benefits of NFB can be used independently to support relief from symptoms of anxiety, or as an adjunct treatment in combination with talk therapy. NFB, on its own, does not heal depression, PTSD or other disorders, but its ability to relieve symptoms in a non-invasive, non-traumatic, psychophysiological way with lasting effects can contribute to remission of symptoms and improved mental well-being. Including NFB in the toolkit of therapeutic treatment for symptoms of anxiety related to various disorders could be a benefit for practitioners, therapists, and even more for people struggling with mental health symptoms like anxiety and stress.

While research in this area is not as robust as for ADHD, biofeedback equipment and its functions, including modulating alpha brainwaves, is cleared by the FDA for relaxation (CFR - Code of Federal Regulations Title 21, n.d.). Relaxation training of various forms, including biofeedback broadly, is one of the most common treatments for anxiety and reactive stress disorders (Manzoni et al., 2008). Relaxation is a broad term that acts as the basis of more specific improvement outcomes for anxiety and stress-related issues. Because the underlying causes of anxiety, stress, depression and other mental health conditions are varied and broad, NFB research covers an interesting gamut of causes and conditions. Even so, related studies show NFB to be effective at reducing symptoms of anxiety.

A 2020 meta-analysis (Anxiety Disorders: Rethinking and Understanding Recent Discoveries, 2020) of 21 studies with 779 participants concluded that neurofeedback is efficacious in the treatment of anxiety and reactive stress disorders. The relevant research highlights that regulating alpha brainwaves is an effective treatment for reducing anxiety. (See Appendix A in the full NFB report for more about brainwaves.)

This meta-analysis states: "Although there are many variants of EEG neurofeedback, the most frequently studied of these in the anxiety disorders have focused on increasing alpha waves. Alpha is the dominant EEG rhythm in healthy adults at rest and is associated with a calm, relaxed state. Among patients with panic disorder, alpha is attenuated, though in GAD patients, alpha is increased. Increasing alpha magnitude can produce a calming effect in high-anxious individuals."

Other, more case-specific studies support the proposition that NFB is an effective treatment for symptoms of anxiety.

A 2011 study used NFB to treat people diagnosed with anxiety disorder (Moradi et al., 2011). Following 30 NFB sessions over three months, subjects experienced significant reduction in symptoms. At one year of follow-up, subjects' symptom checklist was in the normal range, meaning they were no longer showing clinical signs of anxiety, and self-reports indicated that they continued to experience relief from symptoms after treatment ended. Similarly, a 2015 study used NFB to treat a cancer patient with anxiety and found significant improvements after 20 NFB sessions as measured by the standard symptom checklist, SCL-90 (Benioudakis et al., 2016). Another 2012 study explored using NFB to reduce anxiety in professional athletes. Twenty professional swimmers participated in 12 NFB sessions and reported significant decreases in anxiety compared to a control group (Faridnia et al, 2012).

In more comprehensive research, D. Corydon Hammond, Ph.D., a psychologist and Professor (Clinical) Emeritus of Physical Medicine and Rehabilitation at the University of Utah School of Medicine conducted a review in 2005, exploring the then current research on NFB as a treatment for anxiety, depression and obsessive-compulsive disorder (Hammond, 2005). While he concluded that more controlled trials were needed, he stated that the research to date warranted considering NFB as an efficacious treatment for anxiety.

Still other research looked at the effects of NFB for GAD. A 2015, quasi-experimental study evaluated NFB as a treatment for patients with GAD versus a control group (Dadashi et al, 2015). After 30 NFB sessions, the NFB group showed improvements in global functioning levels and reduced symptoms of GAD. Along the same lines, a 2010 study compared NFB to antianxiety medication as a treatment for anxiety in 100 patients with psychiatric

diagnoses (Bhat, 2010). The NFB group received treatment 5 times a week for 8 weeks, with follow-ups at 4 and 8 weeks. An interesting outcome was that overall, NFB was almost as effective as pharmacotherapy for symptoms of anxiety, and in female patients, NFB was more effective than medication.

A handful of other studies have explored NFB as a treatment for symptoms of anxiety, PTSD, depression, stress and other emotional and mental conditions. Many of the studies are smaller, but all show promise for, and effectiveness in, relieving symptoms of various conditions. Given the propensity for NFB to be effective as a treatment or adjunct treatment for such symptoms, NFB is a valid option for non-invasive, non-pharmacological treatment for states of anxiety resulting from a host of mental health conditions.

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BRAINFUTURES

BrainFutures was launched in 2015 by the nation's second oldest mental health advocacy organization, the Mental Health Association of Maryland (MHAMD). For more than 100 years, MHAMD has addressed the mental health needs of Marylanders of all ages through programs that educate the public, advance public policy, and monitor the quality of mental healthcare services. Building on this success, and bolstered by a cross-disciplinary advisory board of leading experts, BrainFutures brings together diverse stakeholders, policymakers, funders, and influencers to accelerate and scaffold national adoption of effective practices targeting four main areas: youth, workforce, mental health treatment, and older adults. Breakthroughs in our understanding of the brain have the potential to improve learning outcomes for children, optimize functioning at work, enhance treatment for mental health or substance use problems, and maintain sharp thinking as we age.

BrainFutures writes evidence-based issue briefs and releases recommendations that fill knowledge gaps related to brain-focused applications targeting the above segments of society. These educational resources highlight the latest advances in brain plasticity and how their application is transforming quality of life for people of all ages. Through this process, we not only gain insight from experts and innovators, we also foster support for change, building coalitions and cross-disciplinary collaborations to advance both adoption and access to new breakthrough applications. Ultimately, by informing the public, cultivating influential relationships, and connecting communities of diverse advocates we help propel the change that is needed to make meaningful progress.

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