Double-Blind, Sham-Controlled Randomized Trial Testing the Efficacy of fMRI Neurofeedback on Clinical and Cognitive Measures in Children With ADHD

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Commentary by Dr. Doron Almagor: *This is a well-conducted randomized sham-controlled trial that used functional MRI neurofeedback (fMRI-NF) to assess its potential effectiveness in children with ADHD. The study aimed to control brain activity in the right inferior frontal cortex (rIFC) using fMRI-assessed blood-oxygen-level-dependent responses. However, the study failed to demonstrate significant differences between active and sham neurofeedback, suggesting that the benefits of neurofeedback may be due to nonspecific factors rather than a specific treatment effect. Despite many hopes, and years of research, well-controlled studies have failed to show any benefit for neurofeedback, even when using advanced technologies such as functional MRI. The dearth of evidence supporting the efficacy of neurofeedback raises significant concerns regarding its appropriateness for clinicians to administer or endorse. Given the substantial long-term implications associated with ADHD and the ample data supporting conventional treatment modalities, opting for an unverified therapy rather than effective interventions appears contrary to the best interests of patients. While ongoing advancements in more efficacious approaches to managing ADHD are imperative, it appears that neurofeedback as a treatment for ADHD is no longer tenable.*

ABSTRACT

Objective: Functional MRI neurofeedback (fMRI-NF) could potentially be a novel, safe nonpharmacological treatment for attention deficit hyperactivity disorder (ADHD). A proof-of-concept randomized controlled trial of fMRI-NF of the right inferior frontal cortex (rIFC), compared to an active control condition, showed promising improvement of ADHD symptoms (albeit in both groups) and in brain function. However, comparison with a placebo condition in a larger trial is required to test efficacy.

Methods: This double-blind, sham-controlled randomized controlled trial tested the effectiveness and efficacy of fMRI-NF of the rIFC on symptoms and executive functions in 88 boys with ADHD (44 each in the active and sham arms). To investigate treatment-related changes, groups were compared at the posttreatment and 6-month follow-up assessments, controlling for baseline scores, age, and medication status. The primary outcome measure was posttreatment score on the ADHD Rating Scale (ADHD-RS).

Results: No significant group differences were found on the ADHD-RS. Both groups showed similar decreases in other clinical and cognitive measures, except for a significantly greater decrease in irritability and improvement in motor inhibition in sham relative to active fMRI-NF at the post-treatment assessment, covarying for baseline. There were no significant side effects or adverse events. The active relative to the sham fMRI-NF group showed enhanced activation in rIFC and other frontal and temporo-occipital-cerebellar self-regulation areas. However, there was no progressive rIFC upregulation, correlation with ADHD-RS scores, or transfer of learning.

Conclusions: Contrary to the hypothesis, the study findings do not suggest that fMRI-NF of the rIFC is effective in improving clinical symptoms or cognition in boys with ADHD.

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