J Am Acad Child Adolesc Psychiatry. 2021 Jul;60(7):841-855.
doi: 10.1016/j.jaac.2020.07.906. Epub 2020 Aug 25.

Double-Blind Placebo-Controlled Randomized Clinical Trial of Neurofeedback for Attention-Deficit/Hyperactivity Disorder With 13-Month Follow-up

Neurofeedback Collaborative Group
Collaborators collapse

COLLABORATORS

- **Neurofeedback Collaborative Group**:
L Eugene Arnold, Martijn Arns, Justin Barterian, Rachel Bergman, Sarah Black, C Keith Conners, Shea Connor, Sudeshna Dasgupta, Roger deBeus, Teryll Higgins, Laurence Hirshberg, Jill A Hollway, Cynthia Kerson, Howard Lightstone, Nicholas Lofthouse, Joel Lubar, Keith McBurnett, Vincent Monastra, Kristin Buchan-Page, Xueliang Jeff Pan, Robert Rice, Michelle E Roley-Roberts, Rachel Rhodes, Constance Schrader, Yubo Jeremy Tan, Craig E Williams

- PMID: 32853703

- PMCID: PMC7904968 (available on 2022-07-01)

- DOI: 10.1016/j.jaac.2020.07.906

Abstract

Objective: To determine whether theta/beta-ratio (TBR) electroencephalographic biofeedback (neurofeedback [NF]) has a specific effect on attention-deficit/hyperactivity disorder (ADHD) beyond nonspecific benefit.

Method: In a 2-site double-blind randomized clinical trial, 144 children aged 7 to 10 years with rigorously diagnosed moderate/severe ADHD and theta/beta-ratio (TBR) ≥4.5 were randomized 3:2 to deliberate TBR downtraining versus a control of equal duration, intensity, and appearance. Two early dropouts left 142 children for modified intent-to-treat analysis. The control used prerecorded electroencephalograms with the participant's artifacts superimposed. Treatment was programmed via Internet by an off-site statistician-guided co-investigator. Fidelity was 98.7% by trainers/therapists and 93.2% by NF expert monitor. The primary outcome was parent- and teacher-rated inattention; analysis was mixed-effects regression. Because the expense and effort of NF can be justified only by enduring benefit, follow-ups were integrated.

Results: Blinding was excellent. Although both groups showed significant improvement ($p < .001$, $d = 1.5$) in parent/teacher-rated inattention from baseline to treatment end and 13-month follow-up, NF was not significantly superior to the control condition at either time point on this primary outcome ($d = 0.01$, $p = .965$ at treatment end; $d = 0.23$, $p = .412$ at 13-month follow-

up). Responders (Clinical Global Impression-Improvement [CGI-I] = 1-2) were 61% of NF and 54% of controls (p = .36). Adverse events were distributed proportionally between treatments. The 13-month follow-up found nonsignificant improvement from treatment end for NF (d = 0.1), with mild deterioration for controls (d = -0.07). NF required significantly less medication at follow-up (p = .012).

Conclusion: This study does not support a specific effect of deliberate TBR NF at either treatment end or 13-month follow-up. Participants will be reassessed at 25-month follow-up.

Clinical trial registration information: Double-Blind 2-Site Randomized Clinical Trial of Neurofeedback for ADHD; https://clinicaltrials.gov/; NCT02251743.

Keywords: ADHD; attention-deficit; clinical trials; double-blind; neurofeedback