

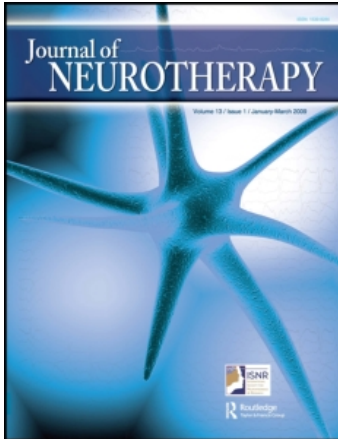
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A Comment on Sherlin, Arns, Lubar, and Sokhadze, 2010

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LETTERS TO THE EDITOR

A Comment on Sherlin, Arns, Lubar, and Sokhadze, 2010

To the Editor:

We thank the *Journal of Neurotherapy* and Drs. Sherlin, Lubar, Sokhadze and Mr. Arns for the opportunity to comment on their “Position Paper on Neurofeedback for the Treatment of ADHD.” As scientists conducting research on the neurofeedback (NF) treatment (Tx) of pediatric ADHD and seeing patients with these problems, we share their hope that NF will one day be shown to be an effective, durable, generalizable, efficient, and cost-effective clinical tool in treating this prevalent, impairing, and chronic disorder. We commend Sherlin et al. (2010) for providing the first updated research summary on this topic since Monastra et al. in 2005. Their review makes an important and timely contribution to the field because, during the intervening 5 years, 11 randomized studies and a meta-analysis have been conducted. Our comments focus on Sherlin et al.’s nine recommendations.

1. “NF is a safe and efficacious Tx intervention for ADHD, meeting the rating of Level 5: Efficacious and Specific.”

Although we expect that NF will be shown to be safe, the safety of NF for the Tx of ADHD is actually still an empirical question as the field has yet to publish evidence to

support or dismiss this assertion. Even though researchers and clinicians frequently report NF as safe and without side effects, none of the 11 randomized studies on NF for pediatric ADHD we recently reviewed systematically measured any adverse events (Lofthouse, Arnold, Hersch, & Hurt, 2010, submitted). Measuring and reporting adverse events is an essential component of any treatment research study because, as Loo and Barkley (2005) noted, all interventions produce some adverse effects in some percentage of the population due to individual physiological differences, errors in Tx delivery, or the complicating presence of comorbidity. Therefore, we recommend that the safety of NF for ADHD be empirically and systematically examined and reported by all future researchers.

Regarding NF being an efficacious intervention for ADHD, meeting a Level 5 rating based on Tx efficacy criteria developed by La Vaque et al. (2002), because of the lack of child-, rater- (e.g., parent, teacher), and experimenter-blinding of Tx assignment (i.e., NF vs. a non-NF control) and sham-control conditions uncovered in our recent review of randomized studies (Lofthouse et al., 20xx) we disagree with this conclusion. Both blinding and sham control, along with randomization, are essential components of experimental research to fully control for potential child-, rater-, and experimenter expectancy effects and nonspecific Tx effects

(i.e., not due to active component of NF) confounding the interpretation of Tx outcome. The technology to conduct a blind and sham-controlled investigation of NF for pediatric ADHD has been available since 2006 (see unpublished studies by deBeus, 2006, and Picard, Moreau, Guay, & Achim, 2006). In addition, we think that the ethical arguments against a sham placebo condition are, on balance, not very compelling and can be thoughtfully and carefully resolved without harm to research participants; in fact, a full-board review by an Institutional Review Board agreed with this.

Although there are no published sham-controlled studies in this area, Sherlin et al. (2010) cited the semiactive control groups (computerized cognitive/attention-skills training) used by Gevensleben, Holl, Albrecht, Schlamp, et al. (2009); Gevensleben, Holl, Albrecht, Vogel, et al. (2009); and Holtmann et al. (2009) as “credible placebo control” (p. 16). These active-control conditions, which use interventions with assumed pre-post Tx gains, are theoretically a more stringent test of NF because they are able to subtract from the NF pre-post benefit whatever pre-post benefit the control treatment yielded, *assuming that the control treatments are proven treatments*. They should also theoretically control for nonspecific placebo effect, *providing the participants and investigators believe that they are as good as NF*. However, it is doubtful that the investigational team believed the control Tx’s were as good as the NF Tx’s. Whether the parents, teachers, and other nonblind raters believed this depended heavily on the orientation and “sales pitch” given them at the beginning and whether they believed this, the details of which are not presented. Further, because the control apparatus and procedure are overtly different than those of NF, double-blinding was not possible. It is doubtful that any of the children, raters, or experimenters thought the control children were getting NF (i.e., “a credible placebo control”), and so these studies could not have controlled for child-, rater-, and experimenter expectancy effects. Another limitation with the existing literature is the lack of studies that have identified and monitored changes in concomitant Tx’s (i.e., medication,

psychotherapy, community and educational services) that maybe causing, moderating, or even mediating positive changes apparently associated with NF.

Considering these issues, the American Psychological Association guidelines for clinical efficacy (Chambless et al., 1998) and our recent review, which showed that only Linden, Habib, and Radojevic (1996) and Levesque, Beauregard, and Mensour (2006) met criteria for Level 3 of these guidelines, we recommend that NF Tx for pediatric ADHD currently be considered as “Probably Efficacious.”

2. ***“NF in the Tx of ADHD has been shown to have long-term effects, lasting from 3 to 6 months. More research is required to investigate the effects after 3 to 5 years of Tx similar to the NIMH-MTA trial.”***

Unfortunately the three studies Sherlin et al. (2010) used to support this recommendation (Heinrich, Gevensleben, Freisleder, Moll, & Rothenberger, 2004; Leins et al., 2007; Gani, Birbaumer, & Strehl, 2008) are all limited in some manner to preclude such a conclusion. Heinrich et al. did not use randomization so any change over Tx, and/or follow-up may have been due to the specific effects of NF but also to selection effects and associated expectations due to participants/parents choosing their preferred Tx group, subject history, regression to the mean, maturation, practice with assessment measures, and/or due to the interaction of any of the aforementioned factors. Leins et al. used randomization but no blinding of raters and experimenters and no sham Tx to control rater- and experimenter expectancy and nonspecific Tx effects. In addition, as Leins and colleagues reported only 4 of 17 significant results between baseline and immediately post-Tx, with the remaining 13 between baseline and 6-month follow-up, unless there was an “sleeper effect,” the positive follow-up results are more likely due to events after NF Tx was terminated. As Gani et al. is a 2-year follow-up of Leins et al., it also suffers from similar limitations. Furthermore, Sherlin et al. concluded (p. 74)

that the follow-up results of the three NF studies are more favorable than those of the 8-year follow-up of the NIMH-MTA study (Molina et al., 2009). However, comparing the briefer follow-ups of the NF studies (3 and 6 months and 2 years) to the long-term follow-up of the MTA (8 years) is invalid. A more suitable contrast would be to the 2 year follow-up of the MTA, which demonstrated a significant but smaller effect of Tx on ADHD symptoms, mostly associated with medication (MTA Cooperative Group, 2004).

We recommend that before researchers “investigate the effects after 3–5 years of Tx similar to the NIMH-MTA trial,” they first demonstrate short-term gains (e.g., 1–6 months) via a randomized, double-blind, sham-controlled study.

3. “The effects of NF appear to have similar effects to stimulant medication for inattention and impulsivity, but more controlled and randomized studies are required to further support this observation.”

We certainly agree that controlled and randomized studies are required. The four studies cited by Sherlin et al. (2010) to support this recommendation (Fuchs, Birbaumer, Lutzenberger, Gruzelier, & Kaiser, 2003; Monastra, Monastra, & George, 2002; Rossiter, 2004; Rossiter & La Vaque, 1995) do indeed report data suggesting that NF appears to have similar effects to stimulant medication for inattention and impulsivity. But unlike the comparative medication studies, none of these four NF studies used randomization or double-blind and/or sham-conditions to control for various confounds. Therefore, at this time it is unknown whether NF has similar specific Tx effects to stimulant medication or if those effects are due to selection effects; nonrandom participant experiences; child-, rater-, and experimenter-effects; other nonspecific Tx effects; and/or to the interaction of any of these factors. In that respect, we feel that Sherlin et al.’s conclusion that the “effects of NF appear to have similar effects to stimulant medication for inattention and impulsivity” implies more than is justified by the data.

4. “Additional research is required to investigate the working mechanism of NF.”

We agree with this recommendation but would highly recommend prioritizing additional research using randomization, double-blind, and sham-controls to examine the primary, and as-yet incompletely answered, question of “Does it work?” before the question of “How does it work?” (p. 74).

5. “Given that NF currently requires multiple Tx sessions, further research should be directed toward improving NF Tx to require fewer Tx sessions (e.g., LORETA NF, ICA NF, Z-score NF).”

We agree with the spirit of this recommendation in terms of making NF more cost-effective, but this needs to be conducted in the context of showing NF is a “Well Established” treatment (Level 4; Chambless et al., 1998) and has long-term effects. In the 11 published and unpublished randomized studies we recently reviewed, the delivery of NF varied greatly from 20 to 40 sessions, 30 to 60 min each, two to five times a week, over a course of 10 weeks to 6 months, interspersed with 4- to 6-week breaks. Only one unpublished study examined session number (Bakhshayesh, 2007), which found that at least 30 sessions were needed to get significant effects. No other study has reported data on the necessary number, length, frequency per week, and overall Tx duration of NF sessions required to obtain clinical improvement and to sustain that improvement over time, so Statement 5 is very timely.

6. “NF is efficacious when inattention and impulsivity are the main problems. When the main complaint is hyperactivity, medication is possibly a better choice given the limited success of NF in this domain. Controlled and randomized studies are required to further substantiate this claim.”

We agree with the need for controlled and randomized studies. This distinction about

differential effect on symptom cluster is a laudable attempt to match the treatment to the patient but is unfortunately premature and goes well beyond the data. It is based on Sherlin et al.'s (2010) comparison of effect sizes (ES) from Faraone and Buitelaar's (2010) meta-analysis of stimulant medication (ES for inattention = 0.84 and for impulsivity/hyperactivity = 1.01) and Arns, de Ridder, Strehl, Breteler, and Coenen's (2009) meta-analysis of NF (ES = 0.81 and 0.4 / 0.69, respectively). Although this seems a logical recommendation based on the reported ES, the ES's for NF are unfortunately confounded by their source. Although Faraone and Buitelaar used placebo-controlled trials and calculated the size of the difference from placebo, Arns et al. used four nonrandomized and six randomized studies, most of them without a placebo control, to calculate these ES. Without randomization, sham controls and double-blinding it is impossible to separate how much of the ES is due to the actual specific effect of NF versus selection effects, subject history, regression to the mean, maturation, practice with assessment measures, nonspecific Tx effect, and/or child-rater-experimenter expectancies. Without these scientific controls we do not currently know the relative efficacy of NF versus medication for inattention, impulsivity, and/or hyperactivity.

7. ***“No differences in NF efficacy have been found between medicated and nonmedicated children; therefore, NF can be utilized in combination with a medication regimen.”***

Unfortunately we were unable to evaluate this recommendation, as Sherlin et al. (2010) did not cite any studies comparing NF efficacy for medicated versus nonmedicated children with ADHD. Although they noted that “four studies compared NF Tx with stimulant medication (Fuchs et al., 2003; Monastra et al., 2002; Rossiter, 2004; Rossiter & La Vaque, 1995)” (p. 9), all of those studies used separate groups receiving either NF or medication but not a group receiving both Tx's, which is also needed for a comparison of NF efficacy between medicated and nonmedicated children.

Before NF is compared to a medication regimen, the field should first show the efficacy of the active feedback component of NF, above and beyond nonspecific Tx effects, via at least one published randomized, sham-blinded control trial. Only then does it make scientific sense to conduct comparison studies with medication. For NF to be subsequently considered a complimentary Tx to medication, incremental effects when added to medication should be demonstrated; to be designated an alternative Tx, similar effects when compared to medicine need to be shown.

8. ***“Licensed health care providers should take necessary educational prerequisites to understand the methods and proper implementation of NF and its appropriateness for the Tx of ADHD.”***
9. ***“When appropriately trained in the planning, implementation, and monitoring of NF, the licensed health care professional should consider including NF as a potential modality of Tx.”***

As almost one third of children with ADHD do not fully benefit from optimal established Tx's (Swanson et al., 2001) and an unknown proportion will not even consider the most effective standard Tx (medication), additional complementary and/or alternative interventions and associated educational prerequisites are indeed greatly needed. Therefore, in principle we agree with Recommendations 8 and 9. However, we also recommend that licensed health care providers take necessary educational prerequisites to understand the methods and proper implementation of other complimentary and alternative interventions for the Tx of ADHD that may be more cost-effective at our current state of knowledge. In two recent reviews on ingestible and noningestible alternative and complementary Tx's for ADHD (Arnold, Hurt, Mayes & Lofthouse, in press; Hurt, Lofthouse, & Arnold, in press), we identified a wide variety of interventions for ADHD, including

NF. We reiterate our recommendation here that clinicians need to evaluate the current level of scientific support, level of interest of the family, and how Safe, Easy, Cheap and Sensible (SECS criterion) the Tx is for that child before considering or rejecting a potential complimentary/alternative Tx.

In sum, we compliment Sherlin and colleagues (2010) for their timely and important position paper on the NF Tx of ADHD. Since the last review in 2005, research studies have dramatically increased in quantity and quality, and we believe that NF is a very promising Tx for pediatric ADHD. However, to fulfill this promise we also believe that peer-reviewed and published randomized, double-blind, sham-controlled trials are needed.

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