

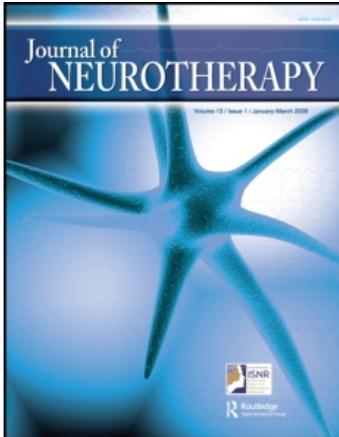
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### A Reply to Lofthouse, Arnold, and Hurt (2010)

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## A Reply to Lofthouse, Arnold, and Hurt (2010)

*To the Editor:*

We applaud the letter to the editor submitted by Drs. Lofthouse, Arnold, and Hurt in this issue, and we appreciate their comments. It is only through interactions like these that we can advance the application of neurofeedback (NF) further to the benefit of ADHD clients. We provide our response to some of the critiques raised by Lofthouse et al. in this letter again following their comments to each of the nine recommendations.

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

Lofthouse et al. note that none of the studies systematically reported on the side effects of NF. This is indeed a weakness in most of the studies, and future studies should in a more systematic way investigate and describe possible side effects to NF. From the earlier studies employing an ABA design it is already clear that when the reverse protocol was used (The “B-lag” of the study) the improvements obtained in ADHD symptoms were reversed (Lubar & Shouse, 1976) and an increase in paroxysmal activity was observed in refractory epileptic patients (Whitsett, Lubar, Holder, Pamplin, & Shabsin, 1982). Furthermore, in a recent letter to the editor by Todder, Levine, Dwolatzky, and Kaplan (2010), the authors report on side effects as a result of NF in a patient with Tinnitus. Also in Hammond and Kirk (2008) and Hammond, Stockdale, Hoffman, Ayers and Nash (2001), it is advised that clinicians should more often report on side effects of NF, and some examples are provided from their experience. So there seems to be an increased consideration for this possibility.

However, as also mentioned in Hammond et al. (2001) by Stockdale: “We have identified certain adverse reactions from EEG Neurofeedback. However, we have also found them to be both rare and transient. They do not seem to be permanent when corrected with EEG neurofeedback treatment” (p. 62). This last statement is important because in NF training a client is seen often (30–40 sessions), and the therapist can still modify the NF protocol to eliminate the side effects. This also underlines the statement made in Recommendation 8 regarding well-educated, licensed health care providers offering NF as a treatment. In a large multicenter study currently under way in Germany by Ute Strehl, such side effects will be systematically monitored (U. Strehl, August 17, 2010, personal communication). Summarizing, we fully agree with the suggestion made by Lofthouse et al. and strongly encourage researchers and clinicians to systematically collect data and report on side effects associated with NF.

Lofthouse et al. disagree with the efficacy rating of Level 5: Efficacious and Specific because blinding and sham control, along with randomization, are essential components to control for expectancy effects. The efficacy template as described by La Vaque et al. (2002), which we used as the main source to reach the aforementioned conclusion, requires “the investigational treatment has been shown to be statistically superior to credible sham therapy, pill, or alternative bona fide treatment in at least two independent research settings” (p. 280). In this definition there is no requirement for “double-blind placebo controlled” but only a “credible sham therapy.”

In our opinion the control groups employed in the Gevensleben et al. (2009), the Holtmann et al. (2009), and the Bakhshayesh (2007) studies meet these requirements. In the following we further explain

our reasoning behind this and address some of the issues raised by Lofthouse et al. In the meta-analysis by Arns, de Ridder, Strehl, Breteler, and Coenen (2009) the need for randomized studies was indeed confirmed, demonstrating that there was a significant difference in effect size (ES) for the domain of "hyperactivity," demonstrating that indeed the effects on hyperactivity were overestimated in nonrandomized studies. In a recent small randomized single-blind placebo controlled study it was also shown that children in the placebo group improved significantly on hyperactivity (Perreau-Linck, Lessard, Lévesque, & Beaugard, 2010), further lending support that nonspecific factors and expectancy effects impact on the domain of hyperactivity. In our position paper we also made clear that the effects for hyperactivity are small and for this domain medication might be a better choice.

The results from another randomized double-blind placebo controlled study by deBeus and Kaiser (in press) also demonstrated that indeed nonspecific effects arise when using a placebo control. This mainly affected the parent ratings in their study (both placebo and NF groups improved based on parent ratings, no significant differences between groups) but not the teacher ratings and neuropsychological performance (IVA). The ES for hyperactive-impulsive (teacher) was medium to low ( $ES = 0.37$ ). The ES for attention were medium (Inattentive, teacher:  $ES = 0.41$ ; IVA attention:  $ES = 0.60$ ).

The effect of randomization in the meta-analysis was not significantly different for the domain Inattention and Impulsivity, suggesting nonspecific factors did not play a major role. Impulsivity was investigated based on CPT performance by children, which can be considered an objective neuropsychological measure, and hence expectancy effects do not play a major role there (in agreement with the findings of deBeus & Kaiser, in press). For inattention a *Diagnostic and Statistical Manual of Mental Disorders*-based rating scale was used, but when comparing the results from the double-blind placebo controlled study from deBeus and Kaiser (in press), their ES fall within the observed confidence intervals

obtained in the meta-analysis, lending further support to the accuracy of these ES.

As another concrete example we address the Gevensleben study in more detail next to specifically highlight how expectancy effects were handled. In the Gevensleben et al. (2009) study it is stated. "Parents were explicitly not informed about the treatment condition of their child and, as a rule, did not enter the room during treatment" (p. 3). Furthermore, they stated, "Both treatments were introduced to the parents and children as experimental, but promising treatment modules for ADHD" (p. 4) Their results also showed that 42% of the parents in the NF group did not reliably estimate the treatment their child underwent, and the obtained ES were similar for the parent ratings as well as the teacher ratings, all suggesting that parents were blinded to treatment whereby expectancy effects were not more favorable to the NF group. Also, the "control" group in this study was in all aspects similar to the NF group. Based on these specifics of the study, we judged this study to have employed a "credible placebo control." Based on these arguments, we still think that Level 5 is justified, more specifically for inattention and impulsivity complaints in ADHD.

Lofthouse et al. argue that the often-mentioned ethical arguments against a placebo group in NF are not very compelling. However, in early studies in epilepsy Lubar also investigated the use of a placebo group and found that the placebo group was characterized by an increased seizure rate. In those studies there were 2 months of non-contingent reward except for EMG inhibits. In that 2-month period, there was an overall increase of seizures by almost 60%. The participants quickly realized that whatever they did to get rewards had no effect and they became very disappointed. In that study they did not break the blind, but after 2 months when the contingent EEG feedback was instituted the participant felt that quickly and began to be able to control the feedback. They were only told that this type of training is challenging and takes time. In the reversal condition they became worse but improved again when

the initial training was reinitiated (Lubar et al., 1981).

This was the same finding in the original work with Shouse in 1974 to 1976, which was the only ABA study done for NFB and ADHD. In fact, Lubar specifically stated, if that study had not worked he may have stopped investigating NFB for ADHD. Now it is not easy to get permission to do reversal studies, so we have to rely on matched, randomized groups with different treatments versus NFB.

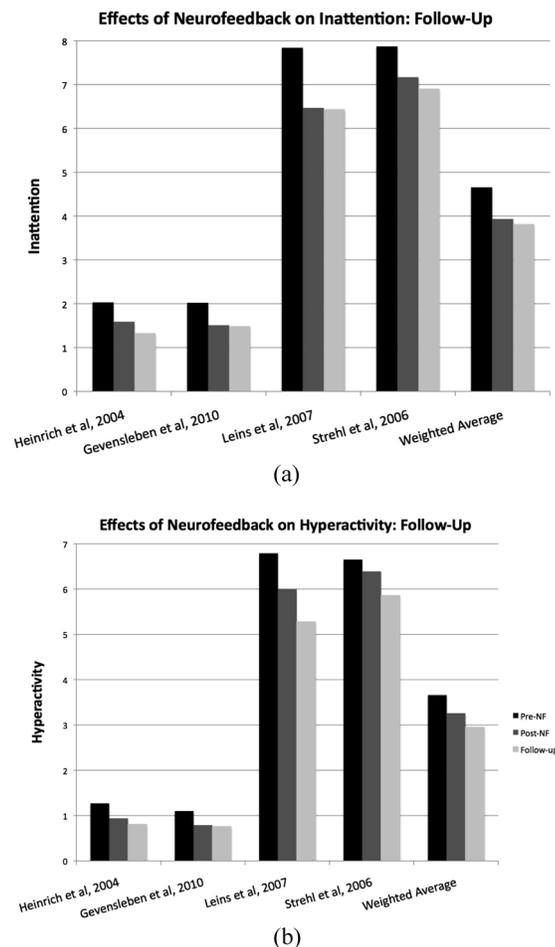
Furthermore, Lofthouse et al. find it a limitation that there is a lack of studies that have identified and monitored changes in concomitant treatments (e.g., medication, psychotherapy, community, and educational services) that maybe causing, moderating, or even mediating positive changes apparently associated with NF. However, in the meta-analysis by Arns et al. (2009) this has been investigated and no effects could be found between studies using children who were medicated or unmedicated; hence it is unlikely that NF exerts differential effects when children are medicated or unmedicated. Furthermore, in the study by Gevensleben et al. (2009) all children were drug free and without concurring psychotherapy for at least 6 weeks before starting the training; hence in this study neurofeedback was not confounded by additional interventions.

**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.”**

Lofthouse et al. question the validity of the results of the three studies initially reported upon due to methodological issues with these studies such as randomization, lack of blinding, and so on. We do agree that more and better research is required to investigate the long-term effects of NF. However, recently the 6-month follow-up data from the Gevensleben et al. (2010) study were published, lending further support to the long-term effects of NF. As previously explained, this study was well controlled

and expectancy effects have not played a major role in this study. In Figure 1 the results are plotted for all four of these studies. Besides the limitations pointed out by Lofthouse et al., we do want to add that the weighted average (averaging all studies with sample size as the weight) shows that the changes after 3 (Heinrich et al., 2004) and 6 months (Gevensleben et al., 2010;

FIGURE 1. The effects of neurofeedback on Inattention (a) and Hyperactivity (b) pretreatment (black), posttreatment (dark gray), and at follow-up (light gray) for four studies that have reported the results at follow-up. Note. The weighted average shows the average for all studies weighted for the number of participants per study. All studies employed 6-month follow-up except Heinrich et al. (2004), who employed 3-month follow-up. Note that for all studies without an exception the effects seem to improve further with time. NF = neurofeedback.



Leins et al., 2007; Strehl et al., 2006) still improve further, this in contrast to medication and placebo effects where the gains made disappear at follow-up without medication. In summary, more research is indeed needed to draw firm conclusions and parallels to the NIMH-MTA results. However, initial results are promising.

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.”***

This conclusion was actually based on the comparison of the meta-analysis on NF with the meta-analysis on stimulant medication by Faraone and Buitelaar (2009). In our position paper we did point out the same methodological issues for the studies mentioned.

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.”***

Lofthouse et al. conclude that the comparison between meta-analysis on NF (Arns et al., 2009) and Medication (Faraone & Buitelaar, 2009) is flawed by the fact that the latter meta-analysis included only double-blind placebo controlled studies. This has also been discussed in more detail under the response to the first recommendation. In the meta-analysis no effect of randomization was found for inattention and impulsivity. In addition, the ES of a recently conducted randomized double-blind placebo controlled study (deBeus & Kaiser, in press) found ES, which laid in the same range as the results reported in the meta-analysis by Arns et al. (2009), further suggesting the ES reported in the meta-analysis is a reliable estimate. Hence this was an attempt to compare the differential efficacy of both treatments. However, as stated in the original recommendation, controlled

and randomized studies are required to further substantiate this claim. So we agree with the suggestions made by Lofthouse et al.

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.”***

Lofthouse et al. were unable to evaluate this recommendation. This too has been spoken to under the response to the first recommendation. And this recommendation was based on data presented in the meta-analysis by Arns et al. (2009) where a post hoc analysis was performed that found no differences in ES between studies where ADHD children were medicated or unmedicated.

All in all we agree with many of the critiques raised by Lofthouse et al., and we advice researchers and clinicians to take careful knowledge of these critiques and be aware of them. The SECS criterion (Safe, Easy, Cheap and Sensible) put forward by Lofthouse et al. is in that sense a good guideline, and if we could we'd like to add that as recommendation number 10 to our original paper!

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