THE JOURNAL OF
CHILD PSYCHOLOGY AND PSYCHIATRY

Journal of Child Psychology and Psychiatry **:* (2009), pp **–** doi:10.1111/j.1469-7610.2008.02033.x

Is neurofeedback an efficacious treatment for ADHD? A randomised controlled clinical trial

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Background: For children with attention deficit/hyperactivity disorder (ADHD), a reduction of inattention, impulsivity and hyperactivity by neurofeedback (NF) has been reported in several studies. But so far, unspecific training effects have not been adequately controlled for and/or studies do not provide sufficient statistical power. To overcome these methodological shortcomings we evaluated the clinical efficacy of neurofeedback in children with ADHD in a multisite randomised controlled study using a computerised attention skills training as a control condition. **Methods:** 102 children with ADHD, aged 8 to 12 years, participated in the study. Children performed either 36 sessions of NF training or a computerised attention skills training within two blocks of about four weeks each (randomised group assignment). The combined NF treatment consisted of one block of theta/beta training and one block of slow cortical potential (SCP) training. Pre-training, intermediate and post-training assessment encompassed several behaviour rating scales (e.g., the German ADHD rating scale, FBB-HKS) completed by parents and teachers. Evaluation ('placebo') scales were applied to control for parental expectations and satisfaction with the treatment. **Results:** For parent and teacher ratings, improvements in the NF group were superior to those of the control group. For the parent-rated FBB-HKS total score (primary outcome measure), the effect size was .60. Comparable effects were obtained for the two NF protocols (theta/beta training, SCP training). Parental attitude towards the treatment did not differ between NF and control group. **Conclusions:** Superiority of the combined NF training indicates clinical efficacy of NF in children with ADHD. Future studies should further address the specificity of effects and how to optimise the benefit of NF as treatment module for ADHD. **Keywords:** Neurofeedback, attention deficit/hyperactivity disorder (ADHD), slow cortical potentials (SCPs), theta/beta training, randomised controlled trial (RCT), EEG.

Attention deficit/hyperactivity disorder (ADHD) is characterised by developmentally inappropriate levels of inattention, impulsiveness and hyperactivity. It is one of the most common psychiatric disorders in children and adolescents (prevalence: about 5%; Rothenberger, Döpfner, Sergeant, & Steinhausen, 2004; Polaczyk, Silva de Lima, Horta, Biederman, & Rohde, 2007). ADHD is often accompanied by impaired social adjustment, academic problems and high likelihood of psychiatric diagnosis leading to lower adaptive functioning in major life activities in adulthood (Gilberg et al., 2004). So far, medication (methylphenidate) is the most effective treatment though it has disadvantages and limitations, like a considerable rate of non-responders, side-effects and reservations against medication (Taylor et al., 2004; Banaschewski et al., 2006). Even in responders, there is still room for improvement.

European clinical guidelines for hyperkinetic disorder recommend a multimodal treatment, encompassing medication, cognitive behavioural and family treatments (Taylor et al., 2004). However, previous child-oriented cognitive-behavioural intervention strategies have not always proven to be sufficiently effective, especially in terms of generalisation and long-term effects (Abikoff, 1991; Pelham, Wheeler, & Chronis, 1998). Thus there remains a need for effective treatment strategies in improving attentional and self-management capabilities in children with ADHD.

In the search for additional or alternative treatment options for children with ADHD, NF emerged as one of the most promising options (Heinrich, Gevensleben, & Strehl, 2007). NF is a neurobehavioural treatment aimed at acquiring self-control over certain brain activity patterns and implementing these skills in daily-life situations. Two training protocols – training of slow cortical potentials (SCPs) and theta/beta training – are typically used in children with ADHD.

A training of slow cortical potentials[1] is related to phasic regulation of cortical excitability. Surface-negative SCPs ('negativities') and surface-positive SCPs ('positivities') have to be generated over the sensorimotor cortex. Negative SCPs reflect increased

Conflict of interest statement: No conflicts declared.

[1] SCPs lasting from several hundred milliseconds to several seconds are related to the level of excitability of underlying cortical regions. They originate in the apical dendritic layers of the neocortex (Birbaumer, Elbert, Canavan, & Rockstroh, 1990).

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excitation and occur, e.g., during states of behavioural or cognitive preparation. Positive SCPs are thought to indicate reduction of cortical excitation of the underlying neural networks and appear, e.g., during behavioural inhibition.

In theta/beta training the goal is to decrease activity in the theta band (4–8 Hz) and to increase activity in the beta band (13–20 Hz) of the electroencephalogram (EEG) which corresponds to an alert and focused but relaxed state. Thus, this training paradigm addresses tonic aspects of cortical arousal.

The rationale of applying these paradigms in ADHD is based on findings from EEG and event-related potentials (ERP) studies. For the contingent negative variation (CNV; a typical SCP), reduced amplitude was measured during cued continuous performance tests (CPT) in children with ADHD (for review see Banaschewski & Brandeis, 2007). This finding may be seen in line with the dysfunctional regulation/allocation of energetical resources model of ADHD (Sergeant, Oosterlaan, & Van der Meere, 1999).

In the resting EEG, increased slow wave activity (theta, 4–8 Hz) and/or reduced alpha (8–13 Hz) and beta (13–30 Hz) activity, especially in central and frontal regions, might be associated with ADHD, probably reflecting under-arousal of the central nervous system (for review see Barry, Clarke, & Johnstone, 2003). However, empirical evidence is contradictory and different findings might depend on technical and motivational factors among others.

On the other hand, notwithstanding a (hypothetical neurophysiological) dysfunction, NF can be seen simply as a tool for enhancing specific cognitive or attentional states in certain situations, as it is practised in peak performance applications in arts or sports (Egner & Gruzelier, 2003; Landers et al., 1991). In this respect, children with ADHD may learn compensatory strategies in NF training, underlining the necessity to support participants in acquiring self-regulation abilities and implementing them in critical life situations.

A series of studies provide evidence for positive effects of NF treatment in children with ADHD. For theta/beta training as well as for SCP training a decrease of behavioural problems and improved cognitive performance have been reported (Drechsler et al., 2007; Fuchs, Birbaumer, Lutzenberger, Gruzelier, & Kaiser, 2003; Heinrich, Gevensleben, Freisleder, Moll, & Rothenberger 2004; Monastra, Monastra, & George, 2002; Strehl et al., 2006).

However, the studies conducted thus far have obvious shortcomings, such as small sample sizes, lack of an adequate control group, no randomisation, mixed multiple intervention strategies or disregard of long-term outcome. These shortcomings preclude unambiguous interpretation or generalisation of the results (Heinrich et al., 2007; Loo & Barkley, 2005).

In the present trial, the main aim was to control for unspecific effects (e.g., the fact that training is an attention-demanding task) and confounding variables (e.g., parental engagement). Therefore, we chose a computerised attention skills training (AST) as a control condition, with both trainings being conceived as similarly as possible. Sample size was calculated to be large enough to reach sufficient statistical power to reveal at least moderate treatment effects. Since theta/beta and SCP training are thought to address different aspects of cortical regulation – both being important for an optimal attentive behaviour (Rockstroh, Elbert, Lutzenberger, & Birbaumer, 1990; Heinrich et al., 2007) – we intended to integrate both protocols in the NF training, also allowing us to compare the protocols at the intra-individual level.

We hypothesised that improvements in the NF group exceeded the training effects in the control group with respect to all ADHD symptom domains. We expected comparable 'global' effects for the two NF training protocols but were also interested to know whether a distinct pattern may occur at the symptom level.

Methods and materials

Subjects

One hundred and two children with ADHD, aged 8 to 12 years (mean age: 9.6 ± 1.2 years), participated in an NF training or an attention skills training (training period: May 2005 to December 2007). Patients of the outpatient departments of the participating clinics with no urgent need for medication were informed about the project and families who had heard about the study from local professionals applied to take part. Subjects were randomly assigned to one of the two study groups (ratio NF:AST = 3:2). There were no pre-training differences between the NF and AST groups concerning demographic, psychological and clinical variables (see Tables 1 and 2).

All patients fulfilled DSM-IV criteria for ADHD (American Psychiatric Association, 1994). Diagnoses were based on a semi-structured clinical interview (CASCAP-D; Döpfner, Berner, Flechtner, Lehmkuhl, & Steinhausen 1999) and confirmed using the Diagnostic Checklist for Hyperkinetic Disorders/ADHD (Döpfner & Lehmkuhl, 2000) by a child and adolescent psychiatrist or a clinical psychologist, supervised by a board-certified child and adolescent psychiatrist. Children with comorbid disorders other than conduct disorder, emotional disorders, tic disorder and dyslexia were excluded from the study. All children lacked gross neurological or other organic disorders. All children were drug-free and without concurring psychotherapy for at least 6 weeks before starting the training. Most of the children (N = 87, see Table 1) were drug-naïve.

The study follows the CONSORT guidelines for randomised trials (Boutron et al., 2008). It was approved by the local ethics committees of the participating clinics and conducted according to the Helsinki

Table 1 Demographic and clinical characteristics of the NF group and the control group: at the pre-training level there were no significant differences between the groups. Dropouts (see text) are not included in the table

	NF group n = 59	AST group n = 35
No. of patients treated by centre (Erlangen/ Göttingen/München)	23/19/17	16/08/11
Age (years; month)	9;10 ± 1;3	9;4 ± 1;2
Sex (boys/girls)	51/8 (86.4%/13.6%)	26/9 (74.3%/25.7%)
IQ (HAWIK-III, Tewes et al. 2000)	106.1 ± 13.2	104.5 ± 12.9
DSM-IV subtype		
Combined type	39 (66.1%)	27 (77.1%)
Inattentive type	20 (33.9%)	8 (22.9%)
Drug-naive	54 (91.5%)	33 (97.1%)
Associated disorders		
Conduct disorder	10 (16.9%)	7 (20.0%)
Emotional disorder	3 (5.1%)	3 (8.6%)
Tic disorder	3 (5.1%)	0 (.0%)
Dyslexia	12 (20.3%)	10 (28.6%)

declaration. Assent was obtained from the children and written informed consent from their parents.

Design of the study

Both trainings consisted of two blocks of 18 sessions (conducted as nine double sessions of about 2 × 50 minutes each, separated by a short break), with two to three double sessions a week, adapted to the families' routine activities during their weekly schedule (2.74 ± .62 double-sessions per week; no significant differences between the groups). Thus, each block lasted for three to four weeks. Pre-training assessment took place during the week prior to the course. Intermediate and post-training assessment was done about one week after the last session of the first and second training blocks, respectively. The NF training consisted of an SCP block and a theta/beta block (balanced order).

Subjects were randomly assigned to the groups by the administering psychologist. Children trained in pairs but children from different treatment groups were not paired together. Each centre prepared time slots for

Table 2 Parents and teachers behaviour ratings (mean values ± standard deviation)

	NF group (n = 59)		AST group (n = 35)			
Behaviour ratings	Pre-training	Change	Pre-training	Change	Effect-size (Cohen's d)	t-test (1-sided)
Parents						
FBB-HKS						
Total score	1.50 ± .45	−.39 ± .37	1.49 ± .50	−.14 ± .44	.60	$p < .005$
Inattention	1.97 ± .51	−.48 ± .47	1.83 ± .52	−.19 ± .55	.57	$p < .005$
Hyperactivity/ impulsivity	1.14 ± .66	−.31 ± .44	1.25 ± .68	−.12 ± .42	.45	$p < .05$
FBB-SSV						
Oppositional behaviour	1.06 ± .66	−.25 ± .44	1.11 ± .66	−.07 ± .53	.38	$p < .05$
Delinquent and physical aggression	.13 ± .13	−.02 ± .12	.15 ± .13	+.03 ± .15	.37	$p < .05$
SDQ						
Total score	16.0 ± 4.8	−2.29 ± 4.95	16.2 ± 4.9	−.03 ± 3.90	.51	$p < .01$
Emotional symptoms	3.54 ± 2.02	−.37 ± 1.89	3.50 ± 2.60	+.03 ± 2.04		
Conduct problems	2.74 ± 1.80	−.39 ± 1.65	3.03 ± 1.68	−.09 ± 1.79		
Hyperactivity	6.93 ± 1.81	−1.29 ± 1.84	7.00 ± 1.76	−.24 ± 1.62	.60	$p < .005$
Peer problems	2.79 ± 2.23	−.24 ± 1.77	2.65 ± 2.02	+.27 ± 1.59	.30	$p < .1$
Prosocial behaviour	7.32 ± 2.28	+.06 ± 1.51	7.32 ± 2.00	−.18 ± 1.81		
Problem situations in family (HSQ-D)	40.6 ± 24.5	−9.3 ± 20.1	30.2 ± 18.3	−5.0 ± 14.1		
Homework (HPC-D)	35.9 ± 9.1	−5.2 ± 9.5	37.8 ± 16.9	−5.2 ± 8.8		
Teachers						
FBB-HKS						
Total score	1.25 ± .59	−.29 ± .33	1.37 ± .66	−.03 ± .47	.64	$p < .01$
Inattention	1.71 ± .62	−.35 ± .51	1.75 ± .59	−.06 ± .64	.50	$p < .05$
Hyperactivity/ impulsivity	.87 ± .82	−.21 ± .42	1.90 ± .89	.01 ± .59	.40	$p < .1$
FBB-SSV						
Oppositional behaviour	.67 ± .76	−.13 ± .37	.74 ± .82	+.01 ± .45	.34	
Delinquent and physical aggression	.06 ± .11	−.01 ± .08	.09 ± .15	−.03 ± .09		
SDQ						
Total score	13.3 ± 6.1	−2.00 ± 4.30	15.2 ± 6.7	−1.35 ± 4.47		
Emotional symptoms	2.00 ± 2.31	−.39 ± 2.17	2.78 ± 2.39	−.82 ± 2.10		
Conduct problems	1.87 ± 1.99	−.36 ± 1.52	2.44 ± 2.31	−.24 ± 1.92		
Hyperactivity	6.18 ± 2.27	−1.01 ± 1.57	7.11 ± 2.65	−.18 ± 1.88	.48	$p < .05$
Peer problems	3.21 ± 2.41	−.22 ± 1.84	2.89 ± 2.89	−.12 ± 2.03		
Prosocial behaviour	5.79 ± 2.80	+.53 ± 2.25	5.61 ± 2.62	−.12 ± 1.73		

Change = post-training minus pre-training values (negative change scores indicate improvement, except SDQ-Prosocial behaviour). Effect sizes (Cohen's d) ≥ .3 are reported. All t-tests and effect sizes refer to comparisons between the groups.

each treatment and the participants were allocated via lots to these treatment slots.

Parental estimations were controlled via evaluation scales ('placebo scales'; questionnaires assessing expectations, evaluation and satisfaction with the treatment). Parents were explicitly not informed about the treatment condition of their child and, as a rule, did not enter the room during treatment.

Assuming a detectable effect size slightly above .5 for the primary outcome measure[2] (German ADHD rating scale, FBB-HKS total score; Döpfner & Lehmkuhl, 2000) and a dropout rate of 5%, we calculated that we needed to include about 100 children to reach a power of .8 (one-sided, .05-level test; ratio NF:AST = 3:2).

Design of the training programs

Both training programs were designed as similarly as possible concerning the setting and the demands placed upon the participants. Treatment of both groups entailed computer-game-like tasks that demanded attention, development of strategies for focusing one's attention and practising of acquired strategies at home and in school. Both treatments were introduced to the parents and children as experimental, but promising treatment modules for ADHD.

The children of both treatment groups completed their trainings in pairs, with each child working at one computer. About three tasks at the computer lasting for about 25–30 minutes were accomplished in one session.

The training programs were administered by the same clinical psychologists with the support of a student assistant who were instructed to take a neutral attitude concerning the effects of the individual training programs. In both trainings, the therapists had to introduce the next task, discuss problems with the task and the use of strategies ('What did you do to succeed?', 'What was your strategy?', 'How did it work?', 'Did you spend much effort?', 'Were you focused or did something distract you?', 'How could you deal with that?'). In addition, the trainers were asked to motivate and praise the children. Thus, the quality and quantity of interaction were comparable for both trainings.

From the 8th session on, children of both groups had to practise one of their strategies in a specific situation for about 10 minutes each day in daily-life situations (e.g., while reading a book, while playing football). Children were instructed to identify situations in which these strategies would be important, aimed at increasing the children's responsibility for attention control in certain situations. Exercises were documented by keeping a log and controlled at the beginning of the next session. Homework was kept identical in quantity and quality between the groups. Parents were instructed to support the children with the transfer of the learned strategies to everyday life. This parent counselling did not exceed two hours.

Neurofeedback training

The neurofeedback system SAM (Self-regulation and Attention Management), which was developed by our study group, was used for neurofeedback training. It contains several feedback animations to keep the training diversified and appropriate for children. During training, children sat in front of a monitor and controlled a kind of computer game by modulating their brain electrical activity. In the course of the SCP training the task was to find appropriate strategies to direct a ball upwards (negativity trials) or downwards (positivity trials). In the theta/beta-protocol a bar on the left of the screen (representing theta activity) had to be reduced while simultaneously a bar on the right (representing beta activity) had to be increased.

In each SCP training session approximately 120 trials were performed. Negativity (50%) and positivity trials (50%) were presented in random order. A trial lasted for 8 seconds (baseline period: 2 s, feedback period: 6 s). Intertrial interval was set to 5 ± 1 s.

Trials of the theta/beta training lasted for 5 minutes at the start of training and were extended to 10 minutes as the training proceeded. Feedback was calculated from Cz (reference: mastoids, bandwidth: 1–30 Hz for theta/beta training and .01–30 Hz for SCP training, respectively, sampling rate: 250 Hz). Baseline values were determined at the beginning of each session (3 minutes). An adjustment within a session was not scheduled. Vertical eye movements, which were recorded with electrodes above and below the left eye, were corrected online using slightly different regression-based algorithms for theta/beta training (Semlitsch, Anderer, Schuster, & Presslich, 1986) and SCP training (Kotchoubey, Schleichert, Lutzenberger, & Birbaumer, 1997). For segments containing artefacts exceeding ±100 μV in the EEG channel and ±200 μV in the EOG channel, no feedback was calculated.

Transfer trials, i.e., trials without contingent feedback, were also conducted (about 40% at the beginning of a training block and about 60% at the end of a training block).

The children of the NF group were required to practise their focused state (which was practised in the sessions) at home, in different situations (one situation per day, e.g., 'try to be very focused while reading', 'try to stay focused on the ball while playing football this afternoon').

Attention skills training

The attention skills training was based on 'Skillies' (Auer-Verlag, Donauwörth, Germany), an award-winning German learning software, which primarily exercises visual and auditory perception, vigilance, sustained attention, and reactivity. In 'Skillies', the children had to sail to several islands. On each island, a defined task – each requiring different attention-based skills – has to be solved; e.g., on an island named 'Coloured Reef', fish of different colours swim from one side of the screen to the other and back. All fish must be the same colour. The colour can be modified by clicking on a fish. With every change of direction the fish change their colour (fixed order). Thus, the main aim of this task is to improve vigilance and reactivity.

[2] This estimation was derived from the effects described in a SCP training study (Heinrich et al., 2004) and a sensorimotor training study (Banaschewski et al., 2001).

The training was complemented by some self-directed interventions from cognitive therapy to assure comparability to NF, i.e., the children were to compile (meta-)cognitive strategies such as focusing attention, careful processing of tasks and impulse control. Corresponding to the NF group, children of the AST group should practise one of the strategies needed to solve a task of the computer-game ('watch like a hawk'), in daily-life situations (as described in the NF section above).

Parameterisation

Parent and teacher ratings were assessed at three points (pre-training, intermediate, post-training). Pre-training questionnaires were evaluated the week before the first training session, intermediate and post-training ratings followed about one week after the last session of the first and second block, respectively.

- German ADHD rating scale (FBB-HKS; Döpfner & Lehmkuhl 2000): The FBB-HKS is a 20-item questionnaire related to DSM-IV and ICD-10 criteria for ADHD and hyperkinetic disorders, frequently used in Germany in the evaluation of medical and cognitive behavioural treatment of ADHD (i.e., Sevecke, Döpfner, & Lehmkuhl, 2004). It was completed by parents and teachers. The severity of each item was rated from 0 to 3. Outcome measures were the main FBB-HKS total score, i.e., the mean value of all items as well as subscores for inattention and hyperactivity/impulsivity. The FBB-HKS total score of the parents constituted the primary outcome measure of the study.
- German Rating Scale for Oppositional Defiant/Conduct Disorders (FBB-SSV; Döpfner & Lehmkuhl, 2000), which allows parameterising oppositional behaviour and delinquent and physical aggression.
- Strength and Difficulties Questionnaire (SDQ; German version; Woerner, Becker, & Rothenberger, 2004), which addresses both positive and negative attributes.
- The Home Situations Questionnaire (HSQ, German version) was used to assess behaviour problems of the child in specific home situations. The HSQ consists of 16 situations in which problematic child behaviour can occur. Parents rate whether the problem behaviour is present in that setting; if so, they rate its severity on a 9-point scale. (Döpfner, Schürmann, & Frölich, 2002).
- Problem behaviour during homework was assessed using the Homework Problem Checklist (HPC, German version). This parent checklist consists of 20 items, rated on a 4-point frequency scale (Döpfner et al., 2002).
- Evaluation scales (Froemke Inventory, 2005; unpublished): a 9-item questionnaire developed by our working group. The first part is made up of items about the assumptions of parents regarding the type of treatment their child receives (neurofeedback, attention skills training, or a combination of both). The second part comprises evaluative questions about the helpfulness of the training (treatment adequacy, satisfaction, and effectiveness) and the motivation of their child on a five-point-scale (0 = in no way/never; 4 = absolute/ever). All items are easy to understand and easy to answer. Psychometric properties of the scales are unexamined.

If post-training ratings of the parents were missing, intermediate ratings were included in the analysis (last-observation-carried-forward approach, LOCF).

Data analysis

Since we had directed hypotheses (larger improvements in the NF group compared to the AST group), one-sided Student's *t*-tests were applied for the analysis of training effects. For these between-group comparisons, change scores (post-training minus pre-training) of parents and teachers ratings were used. Intra-group pre-post comparisons were tested for the primary outcome measure (*t*-test, one-tailed). For comparison of pre-training measures of the NF and AST group and the evaluation of the treatment by the parents ('placebo scales'), two-sided *t*-tests were computed.

For the comparison of the NF protocols, an ANOVA with within-subject factor 'protocol' (theta/beta vs. SCP) and between-subject factor 'order' (of the protocols) was calculated.

To compare the ratio of responders (≥25% reduction of the primary outcome measure) in the NF group and the control group, the odds ratio was calculated.

For all statistical procedures significance was assumed if $p < .05$.

Results

From the 102 children with ADHD who were initially assessed and randomly assigned to a training group, 8 children had to be excluded (NF: $n = 5$; AST: $n = 3$) due to immediate need for medical treatment ($n = 3$), organisational problems of the parents ($n = 2$), loss of motivation ($n = 1$) or protocol violation ($n = 2$). Hence, 94 children were included in the analysis (NF: $n = 59$; AST: $n = 35$) with last-observation-carried-forward in 7 children (NF: $n = 4$; AST: $n = 3$). With mean FBB-HKS total scores of about 1.5, ADHD symptomatology was moderately pronounced in both groups.

Parent ratings

Parent and teacher ratings are summarised in Table 2.

FBB-HKS: Improvement of the NF group in the FBB-HKS total score (primary outcome measure) was superior compared to the AST group ($t(91) = -2.88$; $p < .005$). This effect reached a medium effect size of .60 (Cohen's d).[3] In both treatment groups, a significant improvement resulted (NF: $t(57) = -7.90$; $p < .001$, CI(95%):−.49, −.29; AST: ($t(34) = -1.95$; $p = .03$, CI(95%):−.29, .01).

[3] Considering boys only, the effect size was .56. So, slightly (but not significantly) different gender ratios in the two groups did not affect the main result of our study.

On the subscale level, improvements in inattention and hyperactivity/impulsivity of about 25–30% in the NF group were significantly larger compared to about 10% in the AST group (inattention: $t(91) = -2.71$; $p < .005$); hyperactivity/impulsivity: $t(91) = -2.01$; $p < .05$).

Referring to oppositional and conduct behaviour, the reductions in both *FBB-SSV* subscales in the NF group exceeded the changes in the AST group (oppositional behaviour: $t(91) = -1.82$; $p < .05$; delinquent and physical aggression: $t(91) = -1.81$; $p < .05$).

For the *SDQ* total score as well as for the hyperactivity subscale, the decrease in the NF group was significantly larger than in the AST group (total score: $t(91) = -2.25$; $p < .01$), hyperactivity: $t(91) = -2.71$; $p < .005$). For the remaining SDQ subscales, no significant effects were observed.

Concerning problematic behaviour in family situations (*HSQ-D*) and homework problems *(HPC-D)*, both groups did not differ significantly from each other (HSQ-D: $t(83) = -1.05$, n.s.; HPC: $t(87) = .02$; n.s.). Post-hoc *t*-tests (two-tailed) conducted for the two groups separately indicated improvements in the NF group (HPC: $t(55) = -4.08$, $p < .001$; HSQ: $t(52 = -3.36$; $p < .001$) as well as the AST group (HPC: $t(32) = -3.40$, $p < .002$; HSQ: $t(31) = -2.02$, $p < .1$).

The *responder rate* in the NF group was superior to the rate in the AST group. Thirty children of the NF group (51.7%) and 10 children of the AST group (28.6%) improved more than 25% in the primary outcome measure (odds ratio: 2.68, $p < .05$: CI(95%) = 1.10–6.48).

Parental evaluation/placebo scales: Evaluation scales of 90 participants assessed at the end of the training were available. There was no significant difference between the groups in parents' attitude towards the treatment (e.g., effectiveness: NF group: 3.19 ± .82; AST group: 3.13 ± .90; $t(88) = .30$; $p = .77$) and how parents rated the motivation of their children ('My child does not like the training': NF group: .64 ± .77; AST group: .56 ± 1.13; $t(88) = .37$; $p = .71$).

Forty-two percent of the parents in the NF group and 37% of the parents in the control group could not reliably quote treatment assignment of their child (i.e., these parents voted 'I don't know which training my child attends', 'My child attends a combination of a NF and an AST training' or the parents just estimated the wrong group).

Teacher ratings

For about 70% of the children, pre-training and post-training ratings of the same teacher could be assessed. Missing data, which did not differ significantly between the two groups (χ^2-test: $p = .25$), resulted from school or teacher changes or lack of compliance. For the *FBB-HKS* total score, the reduction in the NF group was superior to the effect in the AST group ($t(60) = -2.55$; $p < .01$). A significant effect was also found for the inattention subscale ($t(60) = -1.94$; $p < .05$) and a trend for the hyperactivity/impulsivity subscale ($t(60) = -1.59$; $p < .1$). Effect sizes of .40 to .64 (medium effect sizes) were in the same range as for the parent ratings (see Table 2).

Analysing FBB-SSV and SDQ ratings of the teachers, a significant effect resulted for the hyperactivity subscale of the SDQ ($t(54) = -1.72$; $p < .05$).

Comparison of theta/beta and SCP training

For both training protocols (theta/beta, SCP), parents rated comparable improvements in the FBB-HKS total score as well as in the inattention and the hyperactivity/impulsivity subscales (see Table 3). Statistics revealed a trend towards better improvement in the FBB-HKS total score, when theta/beta training preceded SCP training ($F(1,50) = 3.00$; $p < .1$).

Discussion

In the present study, the effects of neurofeedback training for children with ADHD were evaluated in comparison to a computerised attention skills training aiming to provide further information about the efficacy of neurofeedback. In contrast to previous studies, the control treatment was designed to parallel the neurofeedback treatment as closely as possible with respect to unspecific factors, using larger

Table 3 *Theta/beta-training vs. SCP-training* (FBB-HKS, parent rating). Each participant of the NF group took part in a SCP- and a theta/beta-protocol block (balanced order). The table shows differences (absolute scores) between the ratings before and after a block

FBB-HKS change	Theta/beta training	SCP training	ANOVA
Total score	−.22 ± .40	−.19 ± .42	Protocol: $F(1,50) = .09$, n.s. Order: $F(1,50) = 3.00$, $p < .1$ P × O: $F(1,50) = .13$, n.s.
Inattention	−.26 ± .52	−.24 ± .56	Protocol: $F(1,50) = .03$, n.s. Order: $F(1,50) = 1.89$, n.s. P × O: $F(1,50) = 1.78$, n.s.
Hyperactivity/impulsivity	−.18 ± .41	−.15 ± .43	Protocol: $F(1,50) = .17$, n.s. Order: $F(1,50) = 1.99$, n.s. P × O: $F(1,50) = 1.31$, n.s.

sample sizes and a randomised group assignment. Neurofeedback was not confounded with additional interventional strategies such as medication, cognitive skills training or parental counselling.

Behaviour ratings by parents and teachers revealed a superiority of the NF training in decreasing ADHD symptomatology. Medium effect sizes of about .6 for the FBB-HKS in parent and teacher ratings indicate that NF effects are substantial and of practical importance. Our results confirm findings of previous NF studies even under strict control conditions.

Positive effects do not appear to be restricted to core ADHD symptoms, but also affected accompanying problems of social adaptation as indicated by the decreases in the FBB-SSV subscales, the SDQ total score, the HSQ and HPC rating.

Control condition

Children in the control group repeatedly practised attentional tasks and their application in daily life. Thus, the control training targets attention management skills directly, i.e., it may have specific aspects (Subrahmanyam, Greenfield, Kraut, & Gross, 2001). Compared to a placebo condition, the use of an attention skills training may have raised the bar for the NF training.

According to scientific standards, a double-blind, placebo-controlled design is suggested to isolate specific effects and is lacking in NF research (Loo & Barkley, 2005). However, such a design, in which participants as well as raters are actually 'blind', is hard to realise for an NF study and must even be questioned for medication studies, which are usually not controlled for the validity of the blinding procedure (Margraf et al., 1991).

Beyond ethical considerations discussed, e.g., in Heinrich et al. (2007), regulation of brain electrical parameters poses certain practical problems for the placebo design. It is difficult to gain mastery over cortical self-regulation. For example, in SCP training up to 60% of the trials are regulated successfully if a subject has appropriate regulation strategies (Leins, 2004), which leaves 40% or more of the trials unsuccessful. Being aware of the possibility of practising a placebo condition may lead to an enhanced impression of uncontrollability, which in turn may result in a loss of motivation and diminished effort (learned helplessness) and thus worsen treatment outcome.

Specific vs. unspecific training effects

The control training was designed to be comparable with respect to training setting, demands upon participants and therapeutic support in general. Since parents of the NF group and the control group did not differ in expectations or satisfaction with the treatment, these factors should not have influenced the results. Thus, our findings support the notion that, first and foremost, specific factors account for the superiority of the NF training.

On the other hand, mainly due to the non-blind design, it is possible that additional factors not considered in our study may have affected the results; e.g., we did not assess the children's attitude towards and satisfaction with the training directly. It cannot entirely be ruled out that expectations, comprehension and effort may have been different between the children of the two groups, even though both trainings were paralleled.

Besides controlling for these factors in future studies, further evidence for the specificity of training effects may be gained by relating neurophysiological measures (e.g., estimates of NF regulation capabilities or pre- to post-training changes in EEG and ERP parameters) to the clinical outcome.

NF training setting

The improvement in the primary outcome measure (FBB-HKS total score) of about 26% after neurofeedback training is comparable to our previous study (Heinrich et al., 2004), as well as behavioural improvements obtained by other groups (Strehl et al., 2006; Drechsler et al., 2007; Fuchs et al., 2003). Actually, we had expected larger effects of about 30–35% since the children had more training sessions and practised both theta/beta training (aiming at tonic aspects of cortical arousal) and SCP training (related to phasic regulation of excitability underlying attentive behaviour). However, one block of 18 sessions might have been too short to build up stable regulation competence. The two protocols were not coordinated but trained in different blocks in order to compare the two protocols at the intra-individual level. To all appearances, several children seemed to be unable to distinguish regulation and transfer strategies of the SCP vs. the theta/beta protocol, but this information was not assessed systematically.

In addition, in order to avoid confounding variables we abstained from some basal elements to enhance effectiveness, such as combination with cognitive/learning strategies and involvement of parents and teachers (Pelham et al., 1998; Drechsler et al., 2007).

Owing to these restrictions of our training setting, it may not be appropriate to indirectly compare the efficacy of NF based on our results with RCTs of other treatment approaches (e.g., long-acting medications with effect sizes of about .6 to 1.0; Banaschewski et al., 2006).

Responders vs. non-responders

As a consequence of the non-optimal training setting, the rate of responders (about 52%) in the neurofeedback group, though superior compared to the control condition (about 29%), fell short of our expectations.

But what differentiates responders from non-responders, i.e., from children who could benefit from NF training but to a smaller degree – or not at all? In a further step it should be investigated if clinical, psychosocial factors as well as neuropsychological and physiological parameters may predict the outcome of NF training. Thus, it could be possible to establish criteria that indicate in which cases NF could be particularly useful as well as identify factors that require particular attention during the training.

General differences between the NF protocols, i.e., theta/beta and SCP training, could not be obtained in our study. However, this does not preclude that an individual child could benefit more from one protocol than the other. Our data also suggest that a certain order of protocols might be advantageous. So the above-mentioned issue of response prediction should also be extended to the question of which factors could influence improvement following a distinct protocol or which combination of protocols might be appropriate for an individual child.

NF in a multimodal treatment setting

Owing to the heterogeneity of children with ADHD and a multiplicity of behavioural and psychosocial factors, it does not seem reasonable to expect sufficient clinical improvement in all children following neurofeedback as the only intervention, particularly if more severely impaired children than those who participated in our study are considered. Further research will show how to combine NF optimally with additional cognitive behavioural and social intervention strategies, parental counselling, and medication within the framework of a multimodal treatment setting. For example, medication might help children benefit more from NF training, or NF could help reduce medication dosage or prevent relapse.

Conclusion

Our results indicate that NF may be considered as a clinically effective module in the treatment of children with ADHD. Further studies are needed not only to replicate our findings but also to control for factors not covered in our study, to further isolate specific effects of NF and to address inter alia how to optimise NF training, also taking the long-term outcome into account.

Note

Trial registry: ISRCTN87071503 – Comparison of neurofeedback and computerised attention skills training in children with attention-deficit/hyperactivity disorder (ADHD). (http://www.controlled-trials.com/ISRCTN87071503).

Acknowledgements

The authors thank Christa Dahlmann, Martin Deinzer, Susanne Wangler and all student assistants for their valuable support as well as all participating families for their contribution and effort. This study was supported by the German Research Foundation (with a joint grant to H.H., G.H.M, and A.R.; HE 4536/2, MO 726/2, RO 698/4).

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Key points

- For children with ADHD, a reduction of inattention, impulsivity and hyperactivity by neurofeedback (NF) has been reported in several studies. To overcome methodological shortcomings of previous studies, we evaluated clinical efficacy in a randomised controlled study using a computerised attention skills training as a control condition.
- For parent and teacher ratings, improvements in the neurofeedback group were superior to those of the control group (medium effect size).
- This is the first randomised controlled trial on neurofeedback in children with ADHD indicating clinical efficacy with sufficient statistical power.

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Manuscript accepted 10 September 2008