1. Neurofeedback has now been shown in a meta-analysis of controlled research studies carried out in a number of countries world-wide, to have the highest level of efficacy for the treatment of ADHD. Arns, M., De Ritter, D., Strehl, U., Breteler, M., Coenen, A. (2009). Efficacy of neurofeedback treatment in ADHD: The effects on inattention, impulsivity and hyperactivity: A meta-analysis. Clinical EEG and Neuroscience, 40(3), 180-189. **ABSTRACT**

Since the first reports of Neurofeedback treatment in ADHD in 1976 many studies have been carried out investigating the effects of Neurofeedback on different symptoms of ADHD such as inattention, impulsivity and hyperactivity. This technique is also used by many practitioners, but the question as to the evidence-based level of this treatment is still unclear. In this study selected research on Neurofeedback treatment for ADHD was collected and a meta-analysis was performed. Both prospective controlled studies and studies employing a pre- and post-design found large effect sizes (ES) for Neurofeedback on impulsivity and inattention and a medium ES for hyperactivity. Randomized studies demonstrated a lower ES for hyperactivity suggesting that hyperactivity is probably most sensitive to non-specific treatment factors. Due to the inclusion of some very recent and sound methodological studies in this metaanalysis potential confounding factors such as small studies, lack of randomization in previous studies and a lack of adequate control groups have been addressed and the clinical effects of Neurofeedback in the treatment of ADHD can be regarded as clinically meaningful. Four randomized controlled trials have shown Neurofeedback to be superior to a (semiactive) control group, whereby the requirements for Level 4: Efficacious are fulfilled (Criteria for evaluating the level of evidence for efficacy established by the AAPB and ISNR). Three studies have employed a semi-active control group which can be regarded as a credible sham control providing an equal level of cognitive training and client-therapist interaction. Therefore, in line with the AAPB and ISNR guidelines for rating clinical efficacy, we conclude that Neurofeedback treatment for ADHD can be considered 'Efficacious and Specific' (Level5) with a large ES for inattention and impulsivity and a medium ES for hyperactivity.

2. In contrast to the lack of long term effects using medication, Neurofeedback has now been shown in controlled research to have a long term beneficial effect on the symptoms of ADHD.

Gani, C., Birbaumer, N., Strehl, U. (2008) Long term effects after feedback of slow cortical potentials and of theta-beta-amplitudes in children with attention-deficit/hyperactivity disorder (ADHD). International Journal of Bioelectromagnetism www.ijbem.org 10, (4), 209-232. This study concludes saying that, “The stability of changes might be explained by normalizing of brain functions that are responsible for inhibitory control, impulsivity and hyperactivity.”

Studies on effectiveness and efficacy of Neurofeedback (NFB) treatment for Attention Deficit Hyperactivity Disorder (ADHD) Even Professionals confuse the two terms, effectiveness and efficacy. We are therefore going to define these two terms and give ADHD examples for each.

Clinical settings can do quality reviews of their interventions. Such reviews should state precisely what is done in a manner that can be replicated by another centre. They should also use standardized tests before and at the end of the intervention to demonstrate change when this

occurs. These standardized instruments compare the client to norms of the same age and sex. Therefore any significant improvement can be assumed to be real and objective. A significant improvement is a statistical calculation that usually means that only 5 out of 100 persons would demonstrate that amount of change purely by chance.

At the ADD Centre we have completed and published two large reviews demonstrating significant positive changes. The first was done on 111 consecutive ADHD clients (1998) and the second on 150 Asperger's plus 9 autistic clients (in press to be published in March 2009). Both these reviews have clearly demonstrated "effectiveness" of the intervention at the ADD Centre. These interventions have combined NFB, BFB, and the teaching of metacognitive strategies. The objective measures used demonstrated significant changes in all of the clients. These tests included the Wechsler Intelligence Scale, the Wide Range Achievement Scale, and Continuous Performance Tests including the Test of Variables of Attention (TOVA) and the Intermediate Visual Auditory (IVA) in addition to subjective measures such as questionnaires and school reports. In our ADHD published review 85% of the subjects, who had started the training with NFB while on medication, no longer required that stimulant medication after just 40 training sessions.

A third less rigorous review was also published comparing the differences in EEG patterns between 165 adult and 96 child clients with ADHD. A fourth clinical review published in a peer reviewed publication demonstrated the effectiveness of combining specific NFB techniques with BFB to allow a patient with severe Parkinson's and Dystonia to control her dystonic symptoms and her Parkinsonian 'freezing' symptom and restore her ability to read novels and to do fine arts and crafts.

A number of authors at other centres have also demonstrated the effectiveness of NFB in the treatment of ADHD in clinical settings. Perhaps the most important reports have come from the University of Tennessee by Dr. Joel Lubar.

B. "Efficacy" refers to the determination of a training or treatment effect derived from a systematic evaluation obtained in a controlled clinical trial (LaVaque, et al., 2002). At the ADD Centre we are completing one such study on the efficacy of NFB for Asperger's syndrome.

Research demonstrating "efficacy" has been done at a number of 'research' centres. Studies for both ADHD and for Seizure disorders have met the necessary criteria for a very high research rating of Level 4: Efficacious.

Level 4, Efficacious, means that these studies have met the research criteria for this level laid out by professional groups such as: the American Psychological Association, The Association for Applied Psychophysiology and Biofeedback, The American Academy of Child Psychiatry, and The International Society for Neurofeedback and Research. These criteria are:

1. In a comparison with a no-treatment control group, alternative treatment group, or sham (placebo) control utilizing randomized assignment, the investigational treatment is shown to be statistically significantly superior to the control condition or the investigational

treatment is equivalent to a treatment of established efficacy in a study with sufficient power to detect moderate differences, and
2. The studies have been conducted with a population treated for a specific problem, for whom inclusion criteria are delineated in a reliable, operationally defined manner, and
3. The study used valid and clearly specified outcome measures related to the problem being treated, and
4. The data are subjected to appropriate data analysis, and
5. The diagnostic and treatment variables and procedures are clearly defined in a manner that permits replication of the study by independent researchers, and
6. The superiority or equivalence of the investigational treatment has been shown in at least two independent research settings.

With respect to ADHD treated with NFB there have been three studies comparing NFB with a wait list control where subjects were randomly placed in the two groups. These studies all demonstrated significant improvement only in the NFB treated group. In one of the studies (Beauregard) demonstrated that the improvements correlated with fMRI changes. In addition, at the time of writing, there have been three studies that have demonstrated that NFB is equivalent or superior to a bone-fide treatment that has been shown to alter the symptoms of ADHD (stimulant medications). There has been one random, placebo controlled, study showing the efficacy of NFB.

One of these studies carried out by Monastra and colleagues is of particular interest to parents and clinicians. In Monastra's study 100 children with ADHD were continued on Comprehensive Clinical Care which included parenting classes, school consults, and stimulant medication. However, 50 of these children were also given NFB. On the completion of 40 sessions of NFB training all 100 children were taken off stimulant medication. After what is called a "wash-out" period of one week retesting was carried out. The 50 children who had received NFB retained the gains they had made over the period of the study. All of the children who did not receive NFB returned to their pre-medication state. The subjects in such a large clinical study could not be randomly assigned to the groups so this has to remain a small but valid criticism from a scientific point of view.

META ANALYSIS

Meta analysis Recent findings demonstrate that Neurofeedback is at the highest level of efficacy of randomized controlled with some multi centre studies

Also other studies (example, ARNS) show that Neurofeedback in contrast to medication, does have long term effects (in contrast to the effects of other approaches such as education and medication)

- The study on Asperger's was published: Thompson, M. & Thompson, L., (2010) Neurofeedback Outcomes in 150 Clients with Asperger's Syndrome and 9 Clients with Autism. Journal of Applied Psychophysiology and Biofeedback, Vol. 35, #1, March, pp 63-81.

Additional Information

The reader who has read research studies will have noted that researchers are forced to use protocols in order to make the intervention exactly the same for each subject. However, it can be argued that a clinical setting should not use a 'protocol' but that every client should be given an individualized treatment plan that corresponds to their specific assessment findings. In the ADD Centre every client is given Neurofeedback corresponding to their individual assessment EEG findings and protocols are not used. This is important in responsible clinical or educational work where the client's training is based on their unique individual assessment and everything is done in treatment to improve the well being of the client. This why clinical setting effectiveness reviews will continue to differ from efficaciousness studies of pure research.

Protocols that have been used in research studies for ADHD include the following:
#1: Site: C3 or C4
SMR 12-15 Hz enhance
Theta 4-7 or 4-8 Hz inhibit
#2: Site C4 (Fuchs, 2003 used 1 &2) for ADHD-C
SMR 12-15 Hz enhance
Beta 22-30 Hz inhibit
3: Sites: Cz – ear
FCz - ear
Cz – Pz sequential
C3 – ear
Theta 4-7 or 4-8 Hz inhibit
Beta 16-20 Hz enhance

Some of the studies demonstrating that NFB is efficacious for ADHD that used the above protocols include:

1. Rossiter & LaVaque (1995).
These authors compared the use of methylphenidate or dextroamphetamine to NFB. There were 23 subjects who were not randomly assigned to the two groups. The NFB group received 20 sessions of NFB (protocol 1 or 3). They found that as long as the drug group was on sufficient medication both groups demonstrated similar significant improvements as measured by a continuous performance test (TOVA) and a questionnaire BASC (reduced hyperactivity and externalizing behaviour problems, and an increase in attention span). There was no significant difference between the two treatments while the patients assigned to the drug group remained on the stimulant medication.

2. Linden, Habib, & Radojevic (1996).
These authors examined clients with ADHD with or without a learning disability (LD). They compared NFB treatment with a waiting list control group. Eighteen subjects were randomly assigned to each group. For NFB they used protocol #3. They demonstrated that only the NFB group showed an average 10 point IQ gain (Kaufman Brief Intelligence Test) and only the NFB group demonstrated a significant reduction in inattention symptoms.

3. Carmody (2001)
This smaller study also compared NFB treatment with a waiting list control group. Eight subjects were assigned to two groups. The NFB protocol used was protocol #1 for between 36 – 48 sessions. Only the NFB group improved on the continuous performance task and in improved attention span. They did not find consistent changes in electroencephalogram (EEG) amplitudes.

4. Monastra, Monastra, George 2002
This study was outlined above. One hundred ADHD subjects were assigned to two groups. Both groups received what was termed Comprehensive Clinical Care (CCC) that included parenting classes, school consults, and medication. One group of 50 subjects also had NFB training sessions. The assignment to each group could not be completely random because some subjects lived a long distance from the treatment centre. The NFB protocol used was protocol #3. This study demonstrated that both groups had a reduction in ADHD symptoms and a significant improvement on a continuous performance test the Test of Variables of Attention (TOVA). In addition the NFB group did demonstrate a significant improvement in an EEG measurement of cortical slowing.

This study went an important step further. They did a one week 'washout' of medication in both groups (all 100 children). They retested everyone and showed that 100% of the group that only received CCC (no NFB) relapsed. However, the NFB group maintained their gains on the TOVA, in the EEG, and their behaviour gains in school.

5. Fuchs, Birbaumer, Lutzenberger, Gryzelier, Kaiser, 2003
These prominent authors are from Germany, Great Britain and the United States. They took subjects diagnosed with ADHD and divided them (not random) into two groups. The first group consisted of 12 subjects who were on Ritalin. The second group comprised 22 subjects who were given NFB for 36 sessions. Protocol #2 was used for the NFB group who were diagnosed as ADHD-H (hyperactive type) and ADHD-C (combined type) and protocol #3 for those diagnosed as ADHD-I (inattentive type). Results of this study showed with the TOVA and behaviour rating scales there was no significant difference between groups as long as the medication group remained on an adequate dosage of mediation.

6. Haywood, Beale, 2003
This smaller study involved seven clients diagnosed with ADHD. It is important in that it was a cross-over design comparing NFB treatment with a placebo. The placebo consisted of NFB with random bandwidths reinforced or inhibited.

Results of this study showed a significant improvement using NFB on a behaviour rating scale (BRS) and in neuropsychological indicators in the 5 subjects who completed training.

7. deBeus, Ball, deBeus, Herrington, 2003 & 2006
This is a particularly interesting study of subjects diagnosed with ADHD. Subjects were randomly assigned to groups. The first group were ADHD-C, n=26, with 14 of the subjects on stimulant medication. The second group were ADHD-I, n=26, with 14 on stimulant medication. This study was double-blind where neither the subject nor the trainer new if the client was

receiving real NFB or a 'sham' placebo NFB (play station) treatment. Those subjects who received real NFB got protocol #1 or #3. All subjects received 40 sessions.

Results of this large study demonstrated significant gains only in the real NFB group. Gains were measured using a continuous performance test (CPT), behaviour ratings, and the quantitative electroencephalogram (QEEG). The QEEG showed that theta decreased while sensorimotor rhythm (SMR) or beta increased.

8. Levesque, Beauregard, Mensour 2006

This study took the entire field of measurement a step further. This group used fMRI measurements before and after the NFB training. The clients diagnosed with ADHD (n = 20) were randomly assigned to two groups 15 to NFB and 5 to a control group. The NFB group received 40 sessions of NFB. The second group remained as a wait-list control. The NFB group received protocol #1 (or #3 if the diagnosis was ADHD-I).

Results demonstrated significant gains on a behaviour rating scale (BRS) and on a continuous performance test (CPT) and with Neuropsychological measures. However, in addition, this study demonstrated that pre-treatment compared to post treatment there were fMRI findings demonstrating activation of important areas in the brains of the ADHD grouping including the: right anterior cingulate, right ventrolateral prefrontal cortex, left caudate nucleus, left thalamus, and left substantia nigra. There was no such activation in the control subjects.

Functional Neuroanatomical Notes: The authors noted that prefrontal areas and the anterior cingulate are involved in attentional processes. They also noted how the capacity to inhibit behaviors or responses that are inappropriate can be studied using Go/No-Go tasks, in which the participant is required to refrain from responding to designated items within a series of stimuli. They have listed fMRI studies that have shown that several prefrontal regions including the anterior cingulate cortex(ACC), dorsolateral prefrontal cortex, orbitofrontal cortex, ventrolateral prefrontal cortex, and the striatum are all involved in this response inhibition.

Beauregard et al concluded that this study demonstrated that NFB has the capacity to functionally normalize the brain systems mediating selective attention and response inhibition in ADHD clients.

9. Zhang, Zhang, Shen 2006

This recent study was a randomized clinical trial. There were 22 children who were treated with NFB 20 of whom were methylphenidate (MPH) non-responders. These were compared with 22 MPH responders who were treated using this medication. The NFB included 4-8 Hz suppression while 16 – 20 Hz was enhanced. There were 3-5 sessions per week for 3 months for a total of 35-40 sessions. Evaluations were carried out at 1, 3, and 6-12 months.

Results in this study using the Conner's Parent questionnaire and a Trail-making speed test demonstrated that at 3 months NFB appeared equally effective compared to MPH. At 6 months the NFB group did better on the trail-making tests and on the Connor's Parent rating scale (CPRS).

10. Meta-analysis of 9 controlled studies: Snyder & Hall (2006) Neurophysiology
This meta-analysis (data from a number of studies are grouped together and analyzed) looked at studies that included 1498 subjects with ADHD comparing them to healthy controls. The grouped data had an effect size (0.8) and sensitivity (few false positives - accuracy of picking out real cases) and specificity (few false negatives – real cases not disguarded) of approximately 94% for theta / beta power ratio. This meant that the diagnosis of ADHD could be accurately confirmed using the EEG power ratio. They found that the QEEG matched or exceeded Child Behaviour Checklist or Behavior Assessment System for Children differentiating ADHD from healthy controls. The sensitivity of rating scales is only about 50-82% and their specificity about 40-70%. In addition they found that reliability was substantially higher for QEEG than the inter-rater reliability of rating scales.

All of the forgoing are just very brief overviews of a few studies. The discerning reader should check the original references for precise data. The exact references for all these studies and many more can be obtained on the website: www.isnr.org.