Abstract

Background: ADHD is one of the most common neurodevelopmental and psychiatric disorders of childhood. NFB is a comprehensive training system that facilitates changes in brain waves. The aim of this study is to assess whether NFB can be considered a treatment modality for ADHD.

Methods: The present study is a clinical trial randomized study that was conducted on 84 patients who were divided into two main groups Group (A): freshly diagnosed cases of ADHD patients who were only receiving sessions of NFB. Group (B): cases of ADHD patients who were receiving both NFB sessions and medications. All participants were treated with methylphenidate capsules with a total dose of 1mg/ kg/ day in the form of long acting capsules. The total dose was between 20- 60 mg. compliance and side effects were recorded. Both groups received 20 sessions of NFB.

Results: There was statistically significant improvement in both groups on neurofeedback therapy with a higher reduction rate in the group receiving combined treatment (neurofeedback and medications) in relation to children receiving neurofeedback therapy alone.

Conclusion: NFB can be considered a treatment modality for improving the symptomatology in children with attention deficit hyperactivity disorder.

Keywords: Attention Deficit Hyperactivity Disorder, Neurofeedback, Theta Beta Ratio.
Introduction:

It has become well known that problems with biological brain function are usually associated with a wide variety of psychological and psychiatric conditions, as well as with the process of aging and a variety of medical conditions. Pharmacological approaches for influencing the brain are well known in the treatment of different psychiatric disorders. However, as both professionals and the public become more aware that psychopharmacology often produces only modest improvements over and above placebo effects in treating psychiatric disorders, there is increasing interest in other methods that may be available for therapeutically influencing brain functions (Kirsch, 2010).

NFB science is attracting renewed interest as a method to self-regulate one's own brain activity to directly alter the underlying neural mechanisms of both cognition and behavior. It does not only promises new avenues as a method for cognitive enhancement in healthy subjects, but also as a therapeutic tool. NFB is considered a comprehensive type of training therapy promoting growth and change at the brain's cellular level, taking science out of the laboratory into the hands of private health professionals. Therefore, NFB can be considered the technology's answer to psychotherapy, cognitive rehabilitation and poor cerebral performance (Demos, 2004).

With variable applications, professionals from different disciplines started adding neuro-therapy to their own practice to augment the healing and personal growth of their patients. Some have made neuro-therapy their first choice and primary treatment modality while others made it only a part of their practice and choices. High-tech brain imaging has opened a large window in understanding what's inside the brain, and we now can understand that the functioning brain can do more than just cognition and memory. Numerous studies have revealed the brain's role in emotional processing, development of self-confidence and central personality traits that are central to our development and existence (Damasio, 1994).

Based on recent methodological and technical progress, as well as on an increasing information about the neural correlates of behavior and cognition, brain-computer interfaces (BCIs) for NFB are attracting growing attention in both the scientific and medical communities as a method to self-regulate one's own brain activity. Currently, NFB can be used in at least three main ways:

1. As a therapeutic tool to normalize patients' deviating brain activity in order to influence their symptoms (Plachtscher and Neuper, 2006)
2. As so-called peak-performance training to enhance cognitive performance in healthy participants
3. As an experimental method to investigate the causal role of specific neural events (such as brain oscillations) for cognition and behavior which is known as brain-state dependent stimulation (Gohathakurta and Dutta, 2016); (Royter and Gharabaghi, 2016).

NFB And Psychopharmacology:

Most patients seeking treatment with NFB may do so for many reasons, one of which may be as an alternative to medications. Many situations exist in which NFB treatment is indicated without concurrent medications. In certain cases, patient symptoms are severe and difficult to manage that they may interfere with the NFB process. Successful engagement in NFB has a number of basic requirements of the patient, and in mental illness these are often disrupted. At least during the early stages of NFB application, certain patients may benefit from psychotropic medications that can curb disturbances from potentially interfering symptoms. Therefore, providers must have an awareness of how medications may influence NFB process and should be aware when to use, decrease or augment them. (David and James, 2014)

Aim Of The Study:

The purpose of the current study is to prove that NFB (using TBR as a prognostic index) is an efficient modality in treatment of ADHD.

Subjects And Methods:

The present study is a clinical trial randomized study that was conducted on 84 patients who were following up at the outpatient clinics of center of special needs, institute of postgraduate childhood studies, Ain Shams University and Right Way clinic. By the standardized psychiatric evaluation they were diagnosed as ADHD according to DSM IV.

The studied children were divided into two main groups:

Group (A): 44 freshly diagnosed cases of ADHD patients who were only receiving sessions of NFB.

Group (B): 40 cases of ADHD patients who were receiving both NFB sessions and medications. All participants were treated with methylphenidate capsules with a total dose of 1mg/ kg/ day in the form of long acting capsules. The total dose was between (20-60) mg.

1. Inclusion Criteria:
   a. Age: 6-18 years.
   b. Sex: Both Sexes.
   c. Average IQ level (90-110) according to Stanford-Binet Intelligence Scales V (SB 5).

2. Exclusion Criteria:
   a. ADHD with any other neurodevelopmental disorder
   b. ADHD with any other chronic disease
   c. History of problematic prenatal, perinatal or neonatal period, disorders of consciousness, head injury with cerebral symptoms, convulsions, headache or tics.
   d. History Of Psychiatric Disorders.

3. Ethical Aspects: Approval of the study by the Ethical Scientific Research Committee, Institute Of Postgraduate Childhood Studies (IPGCS, 2014) in the form of informed written consent from the caregiver and ascent from the child him/ herself.

4. All children in this study were subjected to:
   a. Full history taking.
   b. Thorough clinical examination.
   c. Procedures:
IQ level Stanford-Binet Intelligence Scales V (SB 5).


**NFB Protocol And Data Collection:**

1. EEG recording was performed using a digital cortical scan device Mitsar 201, electrodes were placed according to the international (10-20) system using a 19 electrode cap with a ground electrode at FZ and linked ears reference. All electrodes were adjusted for impedance<10 KOH, input signals were filtered between (0.5 and 50) Hz, and digitized at a sampling rate of 250 Hz. Electro-oculography was used to monitor eye movements horizontally with electrodes next to the right and left eyes, and vertically with electrodes above and below the right eye. EEG was collected while patients seated in a straight back chair during two conditions for ten minutes each: eyes opened and eyes closed.

2. Each child had 20 sessions of NFB, given twice per week, each session single channel EEG was recorded where band ranges for theta and beta were set at 4-8 Hz (theta), and 13-21 Hz (beta) registered at Cz in the eyes opened condition. Theta/beta ratio (TBR) ratio coefficient was calculated by dividing the activity of the slower band by the activity of the faster frequency band.

3. TBR (4-8 Hz/13-21 Hz): Is a measure of the relationship between internal image based processing (slow activity) and sequential language based processing (fast activity). Normal TBR ranges from (1-1.6). (Holger, et al., 2013)

**Results:**

From 106 enrolled patients, 84 patients were included in the study. The flow chart of the patients through the study is presented here in the following flow chart:

![Flow Chart](Image)

1. Enrolled (n=106)
2. Excluded (n=6)
   - Don’t meet the criteria
3. Assessed for Eligibility (n=100)
4. Randomized (n=100)
5. NFB Sessions only
6. Follow Up
7. NFB and Medications
   - Allocated to intervention (n=54)
     - Exceeded allocation intervention (n=51)
     - Did not exceed allocation intervention (n=0)
   - Allocated to control (n=46)
     - Exceeded allocation control (n=41)
     - Did not exceed allocation control (n=0)
8. Loss to follow up (n=0)
9. Analyzed (n=104)
   - Excluded from analysis (n=0)

**Table (1) Flow diagram of the study.**

<table>
<thead>
<tr>
<th>NFB Sessions Only</th>
<th>NFB And Medications</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>Count</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td></td>
</tr>
<tr>
<td>Age (Yrs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range 6-11</td>
<td>6-10</td>
<td>0.398</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td>0.696</td>
</tr>
<tr>
<td>Females</td>
<td>8</td>
<td>18.2</td>
</tr>
<tr>
<td>Males</td>
<td>36</td>
<td>81.8</td>
</tr>
<tr>
<td>Type</td>
<td></td>
<td>0.841</td>
</tr>
<tr>
<td>Combined</td>
<td>16</td>
<td>36.4</td>
</tr>
<tr>
<td>Hyperactive Type</td>
<td>8</td>
<td>18.2</td>
</tr>
<tr>
<td>Inattentive</td>
<td>20</td>
<td>43.3</td>
</tr>
<tr>
<td>IQ</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>85.0±8.9</td>
<td>84.6±7.6</td>
</tr>
<tr>
<td>Range 72-112</td>
<td>70-110</td>
<td>0.826</td>
</tr>
</tbody>
</table>

* T-test for significance,
SD: standard deviation, P<0.05 is considered statistically significant.

This table revealed that there was no significant difference in ADHD core symptoms and socio-demographic status, including both age and sex in both groups. There was also no significant difference in academic skills (IQ mean difference) between the treatment groups at baseline.

![Figure (2) Bar distribution of the studied groups](Image)

Percent distribution of the studied groups according to the 3 subtypes of ADHD where the inattantive type represented the highest percent followed by the combined type and lastly the hyperactive type.

**Table (2) Mixed Model ANOVA test for TBR (2 way repeated measure ANOVA- mixed model)**

<table>
<thead>
<tr>
<th>NFB Sessions Only</th>
<th>NFB And Medications</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td></td>
</tr>
<tr>
<td>First TBR</td>
<td>4.29</td>
<td>0.7</td>
</tr>
<tr>
<td>Last TBR</td>
<td>1.89</td>
<td>0.29</td>
</tr>
</tbody>
</table>

SD: standard deviation, P<0.05 is considered statistically significant.

This table shows the mean and SD for the first and last TBR in both groups before and after NFB treatment, both were statistically significant.

**Table (3) Time effect in both groups**

<table>
<thead>
<tr>
<th>NFB Sessions Only</th>
<th>NFB And Medications</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td></td>
</tr>
<tr>
<td>First TBR</td>
<td>4.29</td>
<td>0.7</td>
</tr>
<tr>
<td>Last TBR</td>
<td>4.29</td>
<td>0.71</td>
</tr>
</tbody>
</table>

* T-test for significance.

This table shows that time effect in both groups was statistically significant.

**Table (4) Interaction effect in both groups**

<table>
<thead>
<tr>
<th>Percent Reduction</th>
<th>NFB Sessions Only</th>
<th>NFB And Medications</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Percent Change</td>
<td>55.03</td>
<td>96.2</td>
<td>60.03</td>
</tr>
</tbody>
</table>

0.035

* T-test for significance.

(The Effect Of Neurofeedback (NFB) ...
This table shows the percent reduction rate in both groups, showing that the percent reduction rate in group B patients was higher than group A.

Table (5) Mixed model ANOVA test for Conners scale (2 way repeated measure ANOVA Mixed model)

<table>
<thead>
<tr>
<th>Groups</th>
<th>NFB Sessions Only</th>
<th>NFB And Medications</th>
<th>P Value</th>
<th>P Value</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Conner's</td>
<td>73.5</td>
<td>5.1</td>
<td>73.3</td>
<td>3.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Last Conner's</td>
<td>60.1</td>
<td>2.9</td>
<td>58</td>
<td>4.1</td>
<td>0.110</td>
</tr>
</tbody>
</table>

SD: standard deviation. P < 0.05 is considered statistically significant.

This table shows the mean and SD for both groups before and after Conner's scale, both were statistically significant.

Table (6) the effect of NFB on the 3 types of ADHD

<table>
<thead>
<tr>
<th>Type</th>
<th>Percent Reduction</th>
<th>Groups</th>
<th>Mean</th>
<th>SD</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined</td>
<td></td>
<td>NFB Sessions Only</td>
<td>52.01</td>
<td>6.78</td>
<td>54.01</td>
<td>11.75</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NFB And Medications</td>
<td>14.89</td>
<td>8.93</td>
<td>16.40</td>
<td>5.09</td>
</tr>
<tr>
<td>Hyperactive</td>
<td></td>
<td>TBR</td>
<td>45.63</td>
<td>8.26</td>
<td>53.95</td>
<td>6.78</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Conner's</td>
<td>15.91</td>
<td>5.04</td>
<td>19.87</td>
<td>6.19</td>
</tr>
<tr>
<td>Inattentive</td>
<td></td>
<td>TBR</td>
<td>61.20</td>
<td>7.93</td>
<td>69.10</td>
<td>7.65</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Conner's</td>
<td>21.27</td>
<td>4.13</td>
<td>25.09</td>
<td>5.15</td>
</tr>
</tbody>
</table>

*P* value for significance.

This table shows a comparison of the reduction rate among the three different types of ADHD. The inattentive type was statistically significant and showed the best effect following NFB whether group A or group B, followed by the hyperactive type which was statistically significant too, whereas the combined type was statistically insignificant.

**Discussion:**

The results of this study revealed that there was no significant difference in ADHD core symptoms and socio-demographic status, including both age and sex.

There was also no significant difference in academic skills (IQ mean difference) between the treatment groups at baseline.

According to the results of the current study, it has shown statistically significant (*P* < 0.001) improvement in both groups after using NFB sessions, regarding the first group taking NFB sessions only (mean and SD of first TBR were 4.29 and 0.7 respectively, while mean and SD of the last TBR were 1.89 and 0.29 respectively), while the results of the other group taking combined therapy showed (mean and SD of the first TBR were 4.79 and 0.71 respectively while that of the last TBR were 1.86 and 0.4 respectively).

Although the improvement took place in both groups, however the results of the combined therapy group showed better improvement as the percent reduction rate (represented by TBR percent change) was higher in the combined therapy group (B).

Neziroglu, et al. (2017) denoted that the best ADHD core symptom improvements were with the combination treatment of NFB and MPH. He stated that combination treatment has its advantages, including reduction in medication dosage and less time required for parents and teachers to spend on behavioral monitoring.

Monastra, et al. (2002) in his study illustrated the differential treatment effects of Ritalin, EEG biofeedback, and parenting style in patients diagnosed with ADHD. Consistent with previous research, his findings demonstrated certain short-term, beneficial effects of stimulant therapy. However, the use of a dismantling design (which incorporated assessment of treatment efficacy independent of stimulant use), permitted clarification of the clinical gains associated with parenting style and EEG biofeedback as well. Overall, the findings of his study are supportive of multimodal treatment models that include parent counseling and EEG biofeedback, in addition to stimulant therapy.

Inmaculada, et al. (2017) in his study supports that combined treatment of ADHD with systematic behavioral training for parents and teachers are the main axis, and depending on the characteristics of each case, we have the power of pharmacology to improve overall inattention and the neurofeedback capacity to also improve control response in cognitive tasks.

Li, et al. (2013) found that pharmacologic treatment combined with NF to be more effective than pharmacologic treatment and NF alone, and to be particularly suitable for children/adolescents with ADHD who showed a poor response to pharmacologic treatment alone or who experienced side-effects to the drugs. He also reported that multimodal treatment with NF and MPH to be effective, and also suggested that dose reduction of MPH could be possible.

Similarly, Fuchs, et al. (2003) showed that NF technique, through improving the sensorimotor rhythm (12-15 Hz) and beta activity, as well as medication (methylenedate), has positive effect on improving inattention and speed and precision of continuous attention. He also reported a significant improvement in ADHD core symptoms after NF treatment in more than 3 out of 4 children with ADHD.

On the other hand, in contrast to our results Gevensleben, et al. (2009) observed that theta/beta protocol NFB has not positive effect on improving the behavioral problems related to disobedience and opposition in ADHD.

Agreeing with his results, came Liens, et al. (2007) comparing the NFB treatment with theta/beta frequencies protocol and he didn't find any significant difference in terms of behavioral or perceptual results in his cases.

Results of this study has found statistically significant decrease in the Conner's scores before and after treatment with NFB. This reflects significant improvement in behavior and cognition.

This agrees with Leins, et al. (2007) who reported significant reduction of scores of Conner's scale over time. In his study, Participants of the Theta/beta group learned to differentiate between activation and deactivation tasks and improved in deactivation tasks in feedback conditions during the treatment. In fact, achievements in activation tasks improved too but not significantly the same. It is important to note, that the Theta/beta ratios in activation tasks were already negative within the first sessions of the treatment. Thus, the fact, that achievements in
activation tasks did not improve significantly does not mean, that participants did not learn to activate. They did learn at a very early stage of the training but showed no improvement during the following sessions, participants showed much improvement in both cognitive and behavioral variables.

Similarly, Gevensleben, et al. (2009) reported that behavior ratings by parents and teachers revealed a superiority of the NFB training in decreasing ADHD symptomatology. Medium effect sizes of about 0.6 in parent and teacher ratings indicate that NF effects are substantial and of practical importance. Positive effects do not appear to be restricted to core ADHD symptoms, but also affected accompanying problems of social adaptation that faced those children.

Results in this study have revealed that the inattentive type of ADHD was the best type responding to NFB therapy.

This agrees with the study done by Samaneh & Azam (2017) who revealed that Neurofeedback can reduce up to 70% of variance ADHD disorders. Neurofeedback has a significant effect on behavioral symptoms, lack of attention and impulsivity, conversely. It seems that it is not successful in reducing symptoms of hyperactivity. These findings are strongly and positively the same as the previous studies like Hilard (2012), Peyre, et al. (2015).

Similarly, Leins, et al. (2007) reported that significant change of IQ level before and after NFB sessions as well as improvement of all variables of attention have been declared in his study.

Significant treatment effects of NF have been confirmed in meta-analyses by Soruga- Barke, et al. (2013). It included eight randomized controlled trials and three well-controlled trials of NFB. Randomized controlled studies of NFB effects in ADHD demonstrated a lower effect size (ES) for hyperactivity, suggesting that hyperactivity is probably most sensitive to non-specific treatment factors used in short-term studies (e.g. time spent with a therapist), which is not the case in nonrandomized controlled studies.

On the other hand, Inmaculada, et al. (2017) in his study supports that the effects of neurofeedback can be mainly observed on hyperactive/impulsive symptomatology of ADHD patients.

Combination treatment has its advantages, including reduction in medication dosage and less time required for parents and teachers to spend on behavior monitoring. However, for sustained long-term improvements aimed at improving the quality-of-life, longer follow-up periods are required.

That’s why although the result of this study showed that combined therapy had a greater impact on ADHD children than NFB alone, yet the reduction rate was not that highly remarkable between the 2 groups and this allows us to think twice in introducing NFB therapy alone first in treating ADHD children, in addition NFB therapy can be also used to decrease the dose of already given stimulant medications.

This agrees with Li, et al. (2013) who recommended reduction of MPH dose when being combined with NFB.

Similarly, Duric, et al. (2012) found in a controlled and randomized clinical trial that neurofeedback treatment seemed to improve the core symptoms of ADHD, as assessed by parental reports. When neurofeedback was administered in conjunction with pharmacological treatment, the originally prescribed medication dose was observed to decrease (Lora & Moreno, 2011).

In addition, the results of studies that aim at self-regulation of Theta, Beta and/or SMR consistently suggest that neurofeedback treatment reduces ADHD symptoms, cognitive measures, e.g. variables of attention and even parents and teachers report behavioral improvements in everyday life, such as decreased impulsivity, hyperactivity and distractibility. Alhambra et al. (1995) demonstrated a reduction or discontinuation of stimulant medications after administration of NFB sessions (Liens, et al.; 2007).

Although the European clinical guidelines for hyperkinetic disorder recommend a multimodal treatment, encompassing medication, cognitive behavioral and family treatments for cases of ADHD, previous child-oriented cognitive-behavioral intervention strategies have not always proven to be sufficiently effective, especially in terms of generalization and long-term effects. Thus there remains a need for effective non-harming treatment strategies in improving attentional and self-management capabilities in children with ADHD (Gevensleben, et al.; 2009).

**Conclusion and Recommendations:**

Owing to the heterogeneity of children with ADHD and a multiplicity of behavioral 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 NFB optimally with additional cognitive behavioral and social intervention strategies, parental counselling, and medication within the framework of a multimodal treatment setting. 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 NFB and to address how to optimize NFB training, also taking the long-term outcome into account.

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تثير النتائج في الجدول السابق إلى وجود فروق ذات دلالة إحصائية بين متوسطات رتب درجات أفراد المجموعة التجريبي، وُجِدَت الفروق بين متوسطات رتب درجات أفراد المجموعة التحليلي في الفئتين الأعلى والمنخفض في درجة الكلية ليحصلت هذه الفروق عند مستوى 0.05، وذلك لصالح المجموعة التجريبي، وهي تشير إلى نجاح وفاعلياً البرنامج التدريبي لجودة الحياة.

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