

SBIR Phase I Grant: Final Report

Summary

The primary objective of the Phase I application has been achieved. An electroencephalograph (EEG) unit has been integrated with an audio visual wave stimulation (AVS) device to provide sound and light stimulation at brainwave frequencies (EEG/AVS) to aid in the treatment of Learning Disabled (LD) children with attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD). The EEG/AVS is portable, inexpensive, simple and easy to use.

An equally important secondary objective was achieved. The efficacy of the EEG/AVS was demonstrated under conditions using both placebo and no treatment control groups. Children in the experimental group showed significantly greater gains in their Verbal IQ scores (approximately ten percent in eight weeks) than did either the attention placebo or the no treatment control group. In addition, behavioral changes (decreases in inattention and impulsivity) were significantly greater in the experimental group. The decreases in the level of activity in the boys in the experimental group closely approached significance. If the use of behavioral level data allowed the classification of p. values between .05 and .10 as "trends", then the amount of decreases in activity could be called a trend. Strictly speaking, however, the decreases in levels of activity did not quite reach acceptable significance levels.

Children in the experimental group did not perform significantly better than the controls on the WRAT-R on the Reading, Spelling and Arithmetic scales. The effects over time of significantly increased levels of cognitive performance and significantly decreased levels of inattention and impulsivity should be reflected in improvement on these measures. If the Phase II application is approved and funded, the planned long term followup will show whether or not such improvements do occur and, if so, are maintained.

The greatest improvement following EEG/AVS training occurred in the areas where, relatively speaking, functioning was lowest prior to training. Children with normal functioning in non-verbal areas and below normal functioning in verbal areas (the majority of the children with LD/ADD/ADHD have this pattern) made very significant improvements in verbal functioning. The children with normal functioning in verbal areas and below normal functioning in

non-verbal areas showed the most increases in non-verbal areas. This finding is in accordance with a previous report (Carter & Russell, 1993).

Data collected from a subset of the overall sample showed a very significant gain in verbal IQ score (4.2) after 20 sessions. Data from all of the experimental group children showed an even larger and equally significant gain in verbal IQ scores (9.3) after 40 sessions. The amount of improvement appears to be strongly related to the number of training sessions.

The changes observed in the children are in areas of major concern to parents and schools. The shift in the pattern of functioning appears to be in the direction of a more relaxed attentiveness where it is easier for learning to occur than when the children are distracted and constantly overstimulated.

The improvements in behavior appear to be similar to those reported as an optimal response to medication. There were no apparent negative side effects of the EEG/AVS training.

If the Phase II application is approved and funded, a major objective will be the determination of the most time and cost effective way for the EEG/AVS training to be delivered to the children in the schools by school personnel.

An Audio-Visual Stimulation Unit With EEG Biofeedback for Treatment of Learning Disabilities

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Approximately 20 percent of school age children perform poorly in school. The most serious manifestations are difficulties in learning to read and spell, problems with written expression, and trouble with basic arithmetic. The effects of learning failure are cumulative and pervasive. Attending school daily and performing poorly, too often result in psychological problems and even further limits performance.

A vicious cycle of poor academic performance too often results in a negative self-image, dislike of schools and eventually dropping out of school. Many of these children develop problems that result in delinquency and persist into adulthood so that problem children become problem adolescents and adults who are a burden to society and to themselves and to their families.

Major social and behavioral symptoms of these learning disabled children are poor attention, impulsivity and hyperactivity (AD or ADHD). Enormous amounts of time and large amounts of money have been spent in the diagnosis and treatment of attention deficit disorder and hyperactivity in attempts to develop effective treatment and teaching strategies.

The most common form of treatment is pharmacological, often through the

use of a stimulant such as methylphenidate HCl (Ritalin). This treatment, however, is not without difficulties as Swanson, et al (1993) noted:

- There is a large placebo effect
- Long term effects are negligible
- Stimulants only suppress symptoms when stimulant treatment is discontinued, behavior reverts to pre-treatment levels
- Many children have adverse reactions to or side effects from stimulants
- Stimulant drugs are not beneficial to 25% to 40% of hyperactive children

Consequently, many parents are very reluctant to put their children on a regimen of drug treatment.

In the past decade, a non-pharmacological, non-invasive form of treatment for learning disabled (LD) boys with and without ADD or ADHD has been developed that used electroencephalographic "brain wave" biofeedback (EEG) (Cunningham, 1981; Lubar, 1991; Tansey, 1984 & 1990; Carter and Russell, 1981 & 1993). It has been found that many LD/ADD children produce larger amounts of low frequency EEG activity (4 - 8 Hz) and smaller amounts of higher frequency activity . (13 - 20 Hz) than normal children do when the two groups are compared. By training children to produce a greater amount of higher frequency activity, Lubar (1991) showed improvements in grade point average, achievement test scores and increased IQ. Others, including these authors, have reported similar results using EEG training.

A major shortcoming of EEG biofeedback is that it is so expensive, time consuming, and professional trainer-intensive. It requires one-on-one treatment by an experienced professional therapist and very expensive equipment. Training time is also quite lengthy, typically up to 70 sessions.

Recently, Carter and Russell (1993) reported a low cost alternative to EEG biofeedback. This takes the form of audio and visual stimulation (AVS) to produce entrainment to preselected brain wave frequencies. Use of this procedure with children produced significant improvement in their achievement and IQ test scores.

The first objective of this project was to develop an inexpensive and portable EEG/AVS device, easily usable by adult monitors without prior

experience with biofeedback equipment, but who could be trained in a short time. Equipment that could be used in the schools by school personnel would drastically reduce the cost per pupil, thereby making it available to more of the children who need it. The device developed for this project uses an individual's continuously varying dominant EEG frequency as a signal to produce continuously varying audio and visual stimulation. This audio and visual entrainment equipment was designed to 1) select the ongoing dominant EEG frequency; and then 2) alternately increase and decrease the leading of the brain wave frequencies by 5% every 30 seconds. This cycle is to continue for 20 minutes. Theoretically, this pattern of alternatively increasing and decreasing the dominant EEG frequency with the AVS will stimulate the brain to use an increasingly normal and broader range of frequencies. This "normalization" would then allow the child to develop more of the higher brain wave frequencies associated with improved cognitive functioning and behavior control.

As such a device was not then available, our first objective was to develop and field test such an instrument. This was completed, and in February 1994 10 satisfactory EEG/AVS units were delivered.

The second objective was to assess the effects of the EEG/AVS training devices on cognitive and behavioral parameters of school age boys diagnosed with LD and ADD. Two factors interfered with our ability to complete the research on the time line originally planned. The first was that there were technical delays in developing the prototype EEG/AVS units. They were not satisfactorily completed and available until February 28, 1994. The area school administrators could not be approached until the units were completed. They wanted to see exactly what was to be expected of them, the children, the teachers and the parents.

The second interference was that each of the schools approached was enthusiastic about the project and the potential for their LD/ADD students. However, their own internal review guidelines could-not proceed until the units were available. Once, they saw the units and how they functioned, approval was rapid. However, one of the committed schools withdrew at the last moment due to local internal problems related to a major school redistricting controversy. It was then necessary to locate another school and follow their approval process.

Finally, two schools were involved, one elementary and one middle school. An equal number of boys were drawn from each school, 40 in all, as follows: 20 experimental, 10 placebo control, and 10 controls. The LD boys were referred

individually and were receiving special education services as learning disabled. Placement into one of the three groups was random after informed consent was obtained from the parents. The form may be found in the appendix. Boys with a history of seizure disorders were excluded.

All boys were administered the following dependent measures one week prior to beginning the EEG/AVS; training and one week immediately following cessation of training:

- Raven's Progressive Matrices Test
- Peabody Picture Vocabulary Test - Revised
- Wide Range Achievement Test - Revised
- Attention Deficit Disorder Evaluation Scale - School

The children in the experimental group received the EEG/AVS training in groups of five. A special, quiet room was made available for the project by the schools. As scheduled daily, the boys entered the room in groups of five and sat in the comfortable chairs provided. The trainer attached the EEG/AVS electrodes, auditory headset, and visual stimulation glasses to each boy, one at a time, and began the training. Training time was for 22 minutes daily for eight weeks or 40 sessions. The boys were given a choice of hand held toys to play with during the sessions.

The placebo control group received an equal amount of time and attention in terms of educational games such as Language with the expectation of improvement, and during which there was some interaction with an adult monitor. The control group was only identified and administered the pre and post test measures. All testing was done by graduate psychology students "blind" to experimental conditions and subject placement. The trainers were students working on a master's degree in school psychology.

Results

Table 1, in Appendix A, presents standard deviations and standard score means of all groups on all dependent test measures. These were analyzed using a two-way analysis of variance (ANOVA) design of groups by trials (Bruning & Kintz, 1987). The groups were experimental, attention placebo (placebo) and control, and the trials were pretest and posttest scores on the dependent test measures. The ANOVA tables for each computation may be found in the

Appendix B.

The verbal IQ (PPVT-R) shows a significant ($p < .01$) interaction between groups and trials. An inspection of table I reveals that this significant effect is due to the 9.2 IQ point gain by the experimental group. The placebo and control groups gained only 1.70 and .40 points respectively. It is concluded that this significant change in the verbal IQ of the experimental group over either the placebo or control groups was due to the AVS training.

In an earlier study, Carter and Russell (1993) demonstrated that the lower of the two IQ's, verbal or non-verbal, showed significant gains following AVS training, while the higher IQ showed no change. This also appears to be true here. There was no significant gain of any group between pretest and posttest on the Ravens, a non-verbal estimate of IQ.

Ten of the 20 experimental boys had significantly lower verbal IQ's than non-verbal. This follows the usual pattern among learning disabled (LD) boys, that approximately 50 percent have significantly lower verbal than non-verbal IQ's. We were unable to locate a sufficient number of lower non-verbal IQ boys for this study. However, we did compare low verbal with not low verbal IQ. A 12 point difference between lower verbal and not lower verbal was arbitrarily chosen. In this case, the 1.6 gain in the not low verbal IQ was not significant ($t = .70 > p .05$). In contrast, the verbal low group showed a 10.2 gain in verbal IQ. This yielded a $t = 3.8669$, $p < .001$. This further supports the previous findings that AVS is helpful in increasing the lower of the verbal or non-verbal IQ. On the reading subtest of the Wide Range Achievement Test - Revised (WRAT-R), all groups showed approximately equal change between pretest and posttest, approximately three standard scores. The same lack of change by all groups was also shown on the Spelling and Arithmetic subtests.

Table 2 shows the results of testing done at the end of twenty sessions with a subset of the larger sample. The eight children in the experimental group showed gains on verbal IQ (4.30) as compared to the gains made by the eight children in the placebo group (2.70), and to those made by the eight children in the control group (.70). Differences were significant ($p < .01$). Differences in Reading were also found ($p < .05$).

Earlier research (Carter and Russell, 1993) has indicated that the effects of EEG/AVS training increase as the number of sessions increases. The increase in Verbal IQ in the experimental group found after twenty sessions

(4.30) and the increase found after forty sessions (9.20) were, in each comparison, significantly greater ($p < .01$) than the changes seen in the placebo and control groups. It is unlikely that test familiarity in the experimental group would account for the far larger changes observed in the experimental group after forty sessions. Only eight of the twenty children in the experimental group were tested after twenty sessions, while sixteen of the twenty children in the control groups were tested at that time. In addition, the children in the placebo group showed a decrease from their Verbal IQ scores after twenty sessions (2.70) to their scores after forty sessions (1.70). Similar decreases were observed in the control group after twenty sessions (.70) and after forty sessions (.40). The pattern of changes observed would be inconsistent with test familiarity as a possible explanation for the increases seen in the experimental group of children.

The total score on the Attention Deficit Disorders Evaluation Scale (ADDES), did produce significant ANOVA interaction between groups and trials. A visual inspection of the total reveals a 6.15 standard score improvement between pretest and posttest for the experimental boys and less than two points for the placebo and control groups. It is concluded that the AVS treatment was instrumental in improving the total ADDES score as perceived by teachers.

There was a significant interaction effect on the Inattention ($p < .05$) and Impulsive ($p < .01$) subscales. A visual inspection of the data suggests that the changes on these subscales were due to the 3.45 gain by the experimental boys on the Inattention scale and 4.95 change on the Impulsive scale. The placebo and control groups showed changes of only .7 and .2 respectively. The conclusion is that the AVS training reduced impulsivity and increased attention, but had no measurable effect on hyperactivity.

ADDES forms were sent home for all boys. However, only four of the 40 were returned. Consequently, only the school form was analyzed.

Since no significant change was found between the placebo and control groups on any dependent measure, it was decided to combine both groups of 10 into one larger control group of 20 for analysis. This gives the same number of boys in the experimental and combined control groups. Again, a two-way ANOVA was computed. There was no improvement above chance fluctuation for the experimental group over the combined control group on the Ravens. The higher IQ, Ravens, did not change due to EEG/AVS training.

The PPVT-R yielded a significant trial ($p < .01$) and interaction ($p < .01$)

effect. An inspection of the data reveals a gain of 8.7 verbal IQ points by the experimental boys and a one-point gain for the combined controls. A t-test revealed significant ($p < .05$) improvement in verbal IQ by the experimental boys between pre- and posttest. This supports results mentioned earlier.

There was a significant ($p < .01$) change by trials on the Reading subtest, but no significant interaction. Both gained slightly less than three points. Essentially, the same may be said for the Arithmetic subtest. Both groups showed some increase in scores, but there was no difference between the groups.

The Spelling subtest yielded significant trials ($p < .01$) and interaction effects ($p < .05$). An inspection suggests that this is due to the 4.4 increase by the experimental boys. The controls gained only .75 points. A t-test between pre- and posttest scores for the experimental group proved not to be significant. So, there was no significant difference in improvement between the two groups.

The results of the ADDES were quite different, yielding significant trials ($p < .01$) and interaction ($p < .05$). Apparently, this was due to the 6.15 increase by the experimental boys and 1.9 increase by the combined controls. A t-test for improvement by the experimental groups was 2.1586 with $p < .01$. It must be concluded that the AVS training resulted in significantly improved behavior as assessed by the total score of the ADDES.

Testing the experimental boys against the combined controls yielded essentially the same results as detailed earlier. Both subscales of Inattention and Impulsivity produced significant trials ($p < .01$) and interaction effects ($p < .01$). In each case this was due to the magnitude of gain made by the experimental group. Both experimental and combined control groups showed improved scores on the Hyperactivity scale but the differences between the two groups were not significant.

There were two discrete age levels within the experimental group as the research was conducted in an elementary and in a middle school. The following is a post hoc analysis of the older versus younger experimental boys on each dependent test variable. This analysis was done to determine if there were significant differences between groups related to, or attributable to, differences in age.'

There was no difference in gain between older and younger boys on the non-verbal Ravens test. On the more verbal PPVT, there was no difference in

gain between the two groups, but both showed improvement ($p < .05$) between pre- and posttest.

All of the academic tests, Reading, Spelling, and Arithmetic, showed no differences between groups in change and no significant change between pre- and posttest.

The ADDES did show significant total improvement ($p < .01$) both younger and older groups, but no difference between the groups. The conclusion is that AVS training appears to be beneficial for school boys of all ages, who have problems in school related to LD/ADD/

To summarize, the following results were found:

- A significant gain in verbal IQ ($p < .01$).
- Increases in the lower IQ (verbal or non-verbal) were very significant ($p < .001$).
- No improvement in the academic areas of reading, spelling, and arithmetic.
- A significant improvement in the total score on the Attention Deficit Disorders Evaluation Scale. Two of the three subtests of the ADDES yielded significant improvement. Inattention and Impulsivity improved beyond chance ($p < .05$). No improvement was observed on the Hyperactivity Scale.
- Essentially the same results were obtained when the two control groups were combined and analyzed with the experimental group.

Discussion

Perhaps the clearest statement that can be made on the basis of the results is that use of the EEG/AVS, a previously unreported, non-invasive, non-pharmacological intervention, with an experimental group of LD/ADD children resulted in significant improvement in their cognitive functioning when compared to attention placebo and no treatment control. Markedly higher gains in Verbal IQ scores were seen in the experimental group (9.20) than were seen in the placebo control group (1.70) or the no treatment control group (.40). The long term positive effects, academic and/or behavioral, on LD/ADD children of an approximately ten percent increase in their Verbal IQ can only be determined by further research.

There is a considerable body of literature, (for example, Weiss and Hechtman, 1993) documenting the long term negative results of failing to treat LD/ADD and LD/ADHD effectively in childhood. The short term **behavioral** effects of the EEG/AVS training on the children as perceived by teachers, is that the children were rated as being more attentive and less impulsive, although appearing no less active. While there are a number of speculative explanations, one likely explanation is related to the bipolar frontal lobe locations of the EEG sensors from which the dominant frequency is derived that controls the rate of stimulation. The changes in Verbal IQ scores are consistent with Increased frontal lobe development and improved cognitive functioning. Whether sensor placements at other locations would result in other changes and other behaviors such as activity levels related to brain functioning in those areas, is a subject for further research. Research in EEG biofeedback (Lubar, 1991 Tansey, 1984) suggests that training of central midline, prefrontal placement or other areas may result in location specific kinds of changes such as decreases in hyperactivity. A treatment tool that could demonstrate a potential for correcting specific deficits in specific areas of functioning would be of interest to nearly all the people and institutions involved in the diagnosis and treatment of academic and behavioral problems in school age LD/ADD children.

Until such capabilities are demonstrated, the results of this research indicate that use of the EEG/AVS produced significant improvements in the areas of lowest functioning. Normally or optimally functioning areas appeared to be unchanged, at least with the number of training sessions used. Earlier work (Carter and Russell, 1993) using photic and auditory stimulation at selected fixed frequencies, reported similar findings, i.e. improvements in the areas of lowest functioning and little or no change in areas of normal functioning. The amount of change between the Verbal IQ scores at twenty sessions (4.30) and that at forty sessions (9.20) suggests the possibility that even more training might result in even more gains. Again, further research is needed.

Implications

The results indicate that the LD/ADD children receiving EEG/AVS training showed *significantly more* improvement in cognitive functioning than those who did not receive it.

Similarly, the children receiving the training were more attentive and less impulsive than those who did not.

The simplicity of the EEG/AVS training and the low cost of the equipment and the personnel to use it makes this training potentially available to all of the approximately three million school age children who might benefit from it.

The effects of improved brain functioning in children, once made, appear to persist or increase over time. This was demonstrated by a one year follow up of a 56 child sample drawn from a three year, 801 child controlled study of biofeedback relaxation training funded by the U.S. Department of Education (Carter and Russell, 1984). Whether this finding is true for this procedure remains to be determined by further research.

The EEG/AVS appears to be a non-invasive, non-pharmacological, low cost, and simple to use potential new treatment for LD/ADD. It has a clear potential for changing the impaired or undeveloped brain function that appears to be one of the major root causes of LD/ADD. The improved brain functioning resulting from use of the AVS should allow LD/ADD children to make more effective use of other treatment and training resources in the schools.

Several important questions remain to be answered by further research. One is whether the improvements found in this research with LD/ADD boys are maintained on long term follow-up. A second is that a significant number of school age girls have LD/ADD problems and we have no knowledge of the effects of EEG/AVS training on them. Currently, very little scientific information exists regarding LD/ADD problems in girls.

Another question is related to the effects of EEG/AVS training on children of different ages. Although this research did not reveal significant differences between boys of different age levels, the number of boys in each group was small. This question needs to be studied with a larger number of subjects to investigate the relationship between growth changes and response to treatment of LD/ADD at different age levels.

Further questions have to do with the possibilities of reducing treatment times and costs. It is anticipated that more detailed knowledge of the change(s) occurring in both EEG frequency and amplitude activity and behavior during treatment would allow treatment to be more precise and even specific to each individual.

Current technology and software permit the use of such specialized

techniques as power spectral analysis and neural network based expert systems to determine the most time and cost effective training procedures. Preliminary exploration of these possibilities are being conducted. Each reduction in the time and cost of the training, such as using school personnel to do the training in school settings, will increase the availability of this procedure and demand for it from both parents and schools. Further research in the areas of time, cost, and specificity of training should be a high priority.

One frequent hallmark of important research in a new area is the number of questions generated by the findings. This research would appear to qualify on that basis.

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