

SBIR Phase II Grant: Final Report

EXECUTIVE SUMMARY AND OVERVIEW

The intent of this project is and has been to develop a safe, low-cost, effective and non-pharmaceutical method of treating attention deficit disorders in children and adolescents. A proprietary device, the AVS/EEG, uses EEG-driven auditory and visual (or photic) stimulation to bring about a stimulation induced neural activation (SINA) in the brain. In a series of studies with boys and one with girls, the repeated use of this device appears to result in significantly increased performance on cognitive tests in both verbal and non-verbal areas. The changes were observed both at the end of training and on 16 months followup for the boys. No followup data is available for the girls. Parents and teachers of the boys rated their behavior as significantly improved although there was considerable variability among the groups. There were no statistical difference between the boys on AVS/EEG and those on Ritalin suggesting that the effects of AVS/EEG may be equivalent to the effects of Ritalin in cognitive areas. The AVS/EEG might be an alternative in cases where medication is ineffective, only partially effective, or undesirable. The absence of any reported side effects with the AVS/EEG might allow it to be considered when there are unacceptable side effects to the use of Ritalin or where compliance with taking it is low.

BACKGROUND AND SUMMARY, PHASE I, YEAR I

The intent of this project is and has been to develop a safe, low cost, effective and non-pharmaceutical method of treating LD/ADD/ADHD children and adolescents.

EEG-driven auditory and visual (or photic) stimulation is used to bring about stimulation induced neural activation (SINA) in the brain. Over time, the repeated use of this proprietary device (an AVS/EEG) appears to result in increased performance on cognitive tests. Improved behavior is seen in children and adolescents as rated by their parents and teachers. The nature and extent of the significant changes found were the apparent basis for the Phase II award, which uses the same dependent measures and training protocols (Russell, 1994).

The underlying concept is that SINA may directly influence brain functioning and behavior. The results of **Phase I, Year I** appear to support this concept in that the children and adolescents made their largest gains in their areas of lowest functioning. For example, children whose verbal IQ scores were significantly lower than their essentially normal performance IQ scores made significant gains on measures of verbal IQ while showing little or no change on their more normal performance IQ scores. In addition, experimental group boys showed greater improvements in behavior, as rated by parents and teachers, than were made by boys in either the attention placebo or no-treatment control group (Russell, 1994).

The overall results form a complex pattern related to the classification of the boys, i.e., as LD only, LD and ADD or LD and ADHD. The relationship(s) between results and classifications emphasize the importance of accurate diagnosis. In addition, the relationships suggested that there may be important similarities among the children *in each classification that are influential in determining the group responses to treatment.

SUMMARY OF PHASE II, YEAR I First Major Objective

A major question for Phase II was to determine if the positive results of the AVS/EEG training were maintained on long-term follow up. The results of a 16 months follow up on the Phase I, Year I boys has been previously reported (Russell, 1995) but are shown here again for ease of reference.

	LD ONLY	LD/ADD	LD/ADD/H
PPVT			
Posttest	.01	NS	.01
Follow-up	.01	NS	.01
RAVEN'S			
Posttest	.01	.01	.05
Follow-up	.01	NS	NS
READING			
Posttest	NS	NS	NS
Follow-up	.01	NS	.05
SPELLING			
Posttest	NS	NS	NS
Follow-up	.01	NS	NS
ARITHMETIC			
Posttest	NS	NS	NS
Follow-up	NS	NS	NS
INATTENTION			
Posttest	NS	.01	NS
Follow-up	NS	.01	.05
IMPULSE			
Posttest	NS	NS	NS
Follow-up	NS	NS	NS
HYPERACTIVE			
Posttest	NS	NS	NS
Follow-up	NS	NS	.05
ADDES TOTAL			
Posttest	.01	NS	NS
Follow-up	NS	.05	.01

These findings are additional support for the concept that the SINA produced by the repeated use of the AVS/EEG brings about long-term changes in brain functioning and behavior rather than just producing brief symptomatic improvement. It should be noted that the LD and ADHD groups who showed significant changes at post testing on the PPVT maintained them at the same level of confidence ($p < .01$) at 16 months followup. Although Reading did not show significant differences in any of the three groups at post test, the LD and LD/ADHD groups showed significant increases in Reading at 16 months follow up. This may be due to the increased verbal IQ.

While all three groups showed significant improvement on their non verbal Ravens at post testing, only the LD group maintained this at 16 months follow up. Some of the apparent inconsistencies in the results may be due to the small numbers in each group. A number of the scores closely approached significance.

Although the LD/ADHD group did not show improvement at post test on the scales of Inattention and Hyperactivity, they did show significant improvements on those scales at 16 months follow up. The ADD group showed significant improvement ($p < .01$) at post test and this was maintained at follow up. This is in accordance with the concept that the children make gains in their areas of lowest functioning and that they continue to make gains after the termination of treatment.

Second Objective

Here, the intent was to determine if effective AVS/EEG training could be done in a school setting by school personnel. The results indicate that the training can be done in small groups of 5 to 6 children in the schools by appropriately trained personnel for a very low cost per treatment per child. These results will be further amplified in the discussion section of this report.

Third Objective

Here, the question was whether or not the effects of the AVS/EEG training on school age LD/ADD girls were similar to those observed in boys. Because of

delays in receiving Institutional Review Board approval of the University of North Texas (the cooperating institution), this objective was reached in Year II, Phase II rather than in Year I, Phase II as originally planned. The results are presented and discussed in the following Phase II, Year II section of this report.

Fourth Objective

In order to partially test the replicability of our first year findings, a second group of LD/ADD/ADHD boys was studied during Phase 11, Year I (Russell, 1995) using the same dependent measures and training protocol used during Phase I, Year I. There was an important difference. The experimental group boys received approximately 25 training sessions rather than the 40 sessions that were intended. School activities such as test days, teacher work days and the end of the school year precluded their receiving 40 sessions. Although the number of training sessions were only 62% of the number received in the Phase I, Year I study, significant gains were observed.

Briefly, the results may be summarized as follows:

The LD group showed significant improvement in both verbal and nonverbal IQ as estimated by the PPVT and Ravens. They also showed significant improvement on the Inattention and Total scores of the ADDES.

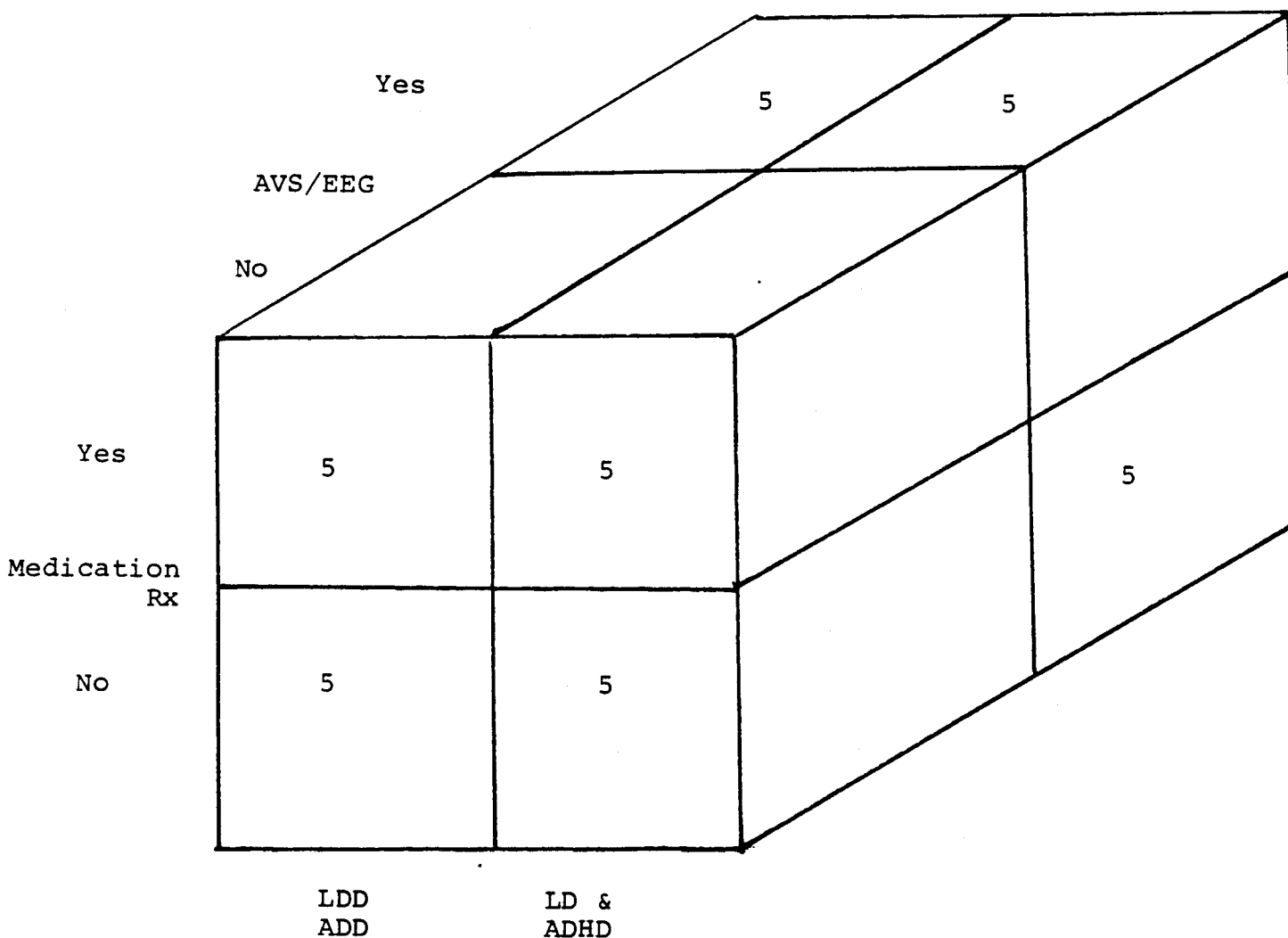
The ADHD group improved significantly on the verbal and non-verbal IQ estimates but showed no improvement on the ADDES.

Details of the changes have been previously reported (Russell, 1995).

PHASE II, YEAR II RESULTS Third Objective

Phase II, Year II Results

The primary objective of Phase II, Year II was to compare and contrast the effects of AVS training with the effects of Ritalin in ADD and ADHD boys. On the following page is the research model. This allows for the following comparisons to be made:



Experimental Model

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There were five boys randomly placed in each cell. Each LD boy was referred to the research program by his pediatrician after being diagnosed as Attention Deficit Disorder (ADD) or Attention Deficit Hyperactive Disorder (ADHD). Statistical treatment involves a 3-way analysis of variance with repeated measures.

1. LD/ADD with no medication (Rx) and no AVS training.
2. LD/ADD with no Rx but with AVS training.
3. LD/ADD with both Rx and AVS treatments.
4. LD/ADHD with no Rx and no AVS.
5. LD/ADHD with no Rx but with AVS training.
6. LD/ADHD with both Rx and AVS.
7. Total LD (ADD & ADHD) with no Rx and no AVS.
8. Total LD (ADD & ADHD) with Rx and no AVS.
9. Total LD (ADD & ADHD) with no Rx but with AVS.

We were unable to access boys to receive neither Rx nor AVS. There was no payoff for them or their parents to agree to the research conditions. Consequently, Groups 1, 4 and 7 were not available for analysis.

The school age boys for this investigation were referred by the Pediatric Department of The University of Texas Medical Branch in Galveston, Texas (UTMB). For this study, the AVS training was conducted by an experienced and centrally located professional at UTMB. The procedure was as follows:

1. An LD child upon being diagnosed by a UTMB pediatrician as ADD or ADHD was referred to the project if Ritalin was to be prescribed. The parents

were given an opportunity to participate after being given a written and oral description of the study and of the expectations. An Informed Consent document was made available for signature if they agreed to have their child participate. The boy was then randomly placed within the research model.

2. Subjects were administered the dependent test measures immediately before treatment, immediately after treatment, and four weeks following termination of treatment.

3. The subjects received the prescribed treatment for eight weeks. Those receiving Rx followed the instructions prescribed by the pediatrician.

4. The following tests were used as dependent measures to assess the effects of the treatments:

- > Peabody Picture Vocabulary Test (PPVT)
- > Raven's Progressive Matrices Test (Ravens)
- > Attention Deficit Disorder Evaluation Scale (ADDES - School Edition)
- > Attention Deficit Disorder Evaluation Scale (ADDES - Home Edition)

Both editions of the ADDES have the following subscales: Impulsivity, Attention, and Hyperactivity.

Surprisingly, scores on the ADDES were not made available. The parents and teachers simply did not fill in the questionnaires in any consistent manner. This is regrettable as the positive behavioral changes found in our earlier studies were an important part of this investigation.

The raw scores for each subject in each group are in the Appendix. Of the tests used, only WRAT-R and Raven's showed significance (P. <.001 level). For the AVS only boys, WRAT-Reading standard scores increased from 105.1 on the pretest to 111.7 on the Posttest and 118.7 four weeks following the end of treatment (Posttest 2) while the Ravens increased from 105.9 to 115.0 between pretest and

Posttest ($P. < .001$). No other statistical significance was obtained. Of those receiving Rx only the Ravens increased significantly ($P. < .05$) between pretest and Posttest. For the ADHD Rx group, the WRAT-Arithmetic scores showed a near significant decrease ($P. < .06$) between pretest and Posttest. The scores of the ADD boys remained essentially the same.

Although these results appear to be minimal, an inspection of the "Summary of Results" on the following page yields some possibly interesting information.

Of those receiving Rx only, all PPVT scores showed a decline between pretest and Posttest while all groups receiving AVS training showed an increase, although not significant. Of those boys receiving both AVS and Rx, all scores increased from pretest to Posttest. In an earlier investigation, Phase II, Year I, an increase of 5.06 and 6.15 points on the PPVT was significant at the $p < .05$ and $P < .01$ level, respectively. In this study, the ADD boys increased by 8.4 points when receiving only AVS training. When the ADD and ADHD boys are combined, the ADD/ADHD boys who received both AVS and Rx had an 8.4 increase on the PPVT. None of these increases were statistically significant. This is probably due to having 10 subjects in each group in the earlier study as opposed to five in this one.

In a like vein on Ravens, the gains of all of the Rx only groups would not have been significant in the earlier study, whereas all groups receiving the AVS training (with and without Rx) showed a magnitude of increase that would have been significant with a larger N. Following are lists of the magnitude of increases between pretest and Posttest of selected variables:

	AVS Only	AVS & Rx	Rx Only
ADD/ADHD	12.6	13.4	7.0
ADD	14.0	10.6	9.2
ADHD	9.6	13.4	4.8

Neither WRAT Spelling nor Arithmetic showed such changes.

It should be remembered that the above increases for pretest to posttest are NOT statistically significant. There does, however, appear to be a pattern for the ADD and ADHD boys who received AVS training with and without Rx to show larger changes between pretest and posttest than those boys receiving Rx only. There is a possibility that a synergistic interaction between AVS and Rx may exist.

One of the remaining objectives was to determine the effects of the AVS/EEG training on school age LD/ADD girls. To establish replicability, a cooperating researcher and institution (Dr. C. Chandler at the University of North Texas at Denton) was chosen to conduct this part of the research with subject selection, training, data collection and analysis being done at the institution. A summary of the findings is shown below and a detailed analysis of the statistical treatment is attached.

The girls showed significant increases on both verbal (PPVT) and nonverbal IQ (Raven).

Mean and SD of All Dependent Measures for Girls

	Experimental		Control	
	Pretest	Posttest	Pretest	Posttest
PPVT-R				
Mean	90.17	95.00*	88.00	88.20
SD	15.25	14.20	6.63	5.38
RAVENS				
Mean	90.75	95.33*	98.80	96.00
SD	8.99	11.15	7.03	6.51
READING				
Mean	84.67	90.50	80.80	83.40
SD	13.81	16.35	10.11	10.84
SPELLING				
Mean	87.33	89.42	79.20	79.40
SD	13.05	13.52	6.54	11.41
ARITHMETIC				
Mean	86.42	96.58	93.00	98.00
SD	14.42	14.57	10.75	9.65

*Denotes significant .05 change of experimental group over control group.

Achievement test scores differences between the experimental and control group girls were not significant at post testing as they were with the boys. Behavioral data on the girls is not available. For reasons that are not known, parents and teachers did not complete the rating scales as requested.

Fifth Objective

Here, the intent of this second year of Phase II has been to collect and analyze EEG data to determine the relationship, if any, between brain wave changes and behavioral and cognitive improvement. This data has been collected and is currently being analyzed. The results will be forwarded upon completion.

Sixth Objective.

The final objective, writing a business plan, is based, in part, on the EEG analysis and will be included with the supplement.

DISCUSSION OF RESULTS

The findings of this series of studies appears to support the concept that LD/ADD/ADHD are neurophysiologically based disorders. The findings suggest that repeated use of a neurophysiologically based procedure, stimulation induced neural activation (SINA results in significant improvements on tests of cognitive functioning(IQ). Additionally, the behavioral evidence available indicates improvements in attention and activity levels. Both cognitive and behavioral measures maintain this improvement at 16 months follow up.

There is a pattern in which the greatest gains appear to emerge in the areas of lowest functioning with strong indication that the gains continue after the training has ended.

The improvements in functioning that we found are consistent with those reported by Lubar (1995), Tansey (1993), Linden (1996) and Cartozzo et al (1995) using neurofeedback training. Unfortunately, neurofeedback requires expensive

equipment, highly experienced technicians and is usually done on a one-to-one basis. The AVS/EEG appears to produce similar gains at a much lower cost.

There is other recent and ongoing work in both clinical and basic research areas regarding SINA and its effects on brain functioning. The investigations are being conducted by Drs. Budzynski and Kogan (University of Washington, Seattle), Chandler, (University of North Texas, Denton), Lubar (University of Tennessee, Knoxville), Montgomery (Nova Southeastern University, Ft. Lauderdale) and Rosenfeld (Northwestern). Until more data is available, the theories and data presented here should be regarded with an open-minded skepticism.

The results of this series of studies suggest that use of the AVS/EEG may be a possible new treatment for attention deficit disorders in children and adolescents. It is a non-pharmaceutical, safe, low cost and apparently effective method. There have not been any reports of negative or undesirable side effects. Many of the children have reported enjoying the training sessions. It should be noted, again, that children with a history of seizure activity have been excluded from the studies.

The overall results form a complex pattern related to the classification of the boys, i.e., as LD only, LD and ADD or LD and ADHD. The findings suggest that there may be important similarities among the children in each classification that influence the response of each group to treatment. Accurate diagnoses are likely to be very important in establishing reasons for differential responses to treatment.

The primary objectives of this research have been met, i.e., one, to determine if the AVS/EEG is an effective method of treating LD/ADD/ADHD children and adolescents. The results are consistent across the several studies within this research - significant increases were seen in both verbal and nonverbal cognitive measures and behavior is significantly better as rated by parents and teachers.

A second major objective was to determine if the increases found at post testing were maintained on long-term follow up or merely represented symptomatic gains attributable to high technology placebo effects. The evidence appears to be quite clear -the effects were maintained on a 16 months follow up and there was evidence that some gains continued after treatment had ended.

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The comparison of the effects of the EEG/ADHD with the effects of Ritalin and with the use of both AVS/EEG and Ritalin is less clear, due in part to the sample size. The increase found in all three groups appear to indicate that the effects of AVS/EEG are equivalent to those of Ritalin and the gains found at post testing with the AVS/EEG were maintained at four weeks followup. The data suggest an advantage of the AVS/EEG over Ritalin and a possible synergistic interaction between the two.

A secondary question, i.e., why did the improvements occur, is much less clear although current scientific literature suggest that the increased functioning may be related to the occurrence of faster frequencies in the subjects' EEG activity.

--Harold L. Russell, Ph.D.

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