

DELOS Mind/Body INSTITUTE

Dr. Marshall D. Voris
1755 Santa Fe CC, TX 78404
423 S. Ravinia Dallas, TX 75211

Telephone 512/884-3843 214/337-9220
Fax 512/884-4358 214-337-9220

Dr. Dan Kirsch
Electromedical Products International Inc.
2201 Garrett Morris Parkway
Mineral Wells, TX 76067

November 8, 1995

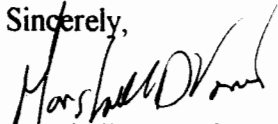
Dear Dr. Kirsch,

Enclosed in the CES study that I completed last month. I hope that you find it useful to your studies and research. It is being submitted to the *Journal of* [REDACTED], so I would ask that you use quotations and references with care.

This afternoon I am meeting with the AIDS researchers regarding the use of CES as a modality to assist HIV+ patients reduce the anxiety and stress of their situation. Information on that meeting will be forthcoming to you soon.

My thoughts and prayers are with you as you continue your work on the PMA, and hope that all your deadlines are met. Take care.

Sincerely,



Marshall D. Voris, Ed.D., Ph.D.
Clinical Director

Final Copy—October 31, 1995

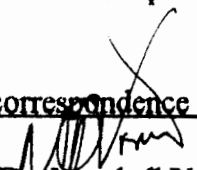
**AN INVESTIGATION OF THE EFFECTIVENESS OF
CRANIAL ELECTROTHERAPY STIMULATION
IN THE TREATMENT OF ANXIETY DISORDERS
AMONG OUTPATIENT PSYCHIATRIC PATIENTS,
IMPULSE CONTROL PAROLEES AND PEDOPHILES**

A TRIPLE BLIND STUDY

By

**Marshall D. Voris, Ed.D., Ph.D.
Clinical Director of Delos Mind/Body Institute
Dallas, Tx and Corpus Christi, Tx**

Address all correspondence and requests to:


**Dr. Marshall Voris
Delos Mind/Body Institute
423 S. Ravinia
Dallas, TX 75211**

Introduction

Anxiety related disorders appear to be related directly to stressful lifestyles, lack of extended family support, economic conditions, and intense sensual stimulation from radio-television, overcrowding, noise pollution, and unreasonable or unrealistic expectations placed on individuals by self or others. Anxiety is best defined as an ongoing and underlying fear related to life as a whole and to specific traits of life. It is estimated that 20% of the population is unable to fly due to flight phobia. At any one time 10 to 15% of the population is reportedly suffering from an anxiety disorder that could benefit from treatment. A significantly large amount of patients being treated for depression in fact have reactive depression. Reactive depression is distinguished from the endogenous and exogenous depression, because it is primarily a coping mechanism for anxiety. The true diagnosis is some form of anxiety, that results in a secondary depression. The depression covers the anxiety and allows the individual the ability to function with some level of success. The increase in the number of anxious patients that are seen in any clinical practice has stirred this researcher's interest in effective treatment modalities for anxiety. There appears to be several traditional treatment modalities available including psychopharmacological treatment with such things as Triavil and Valium. Cognitive restructuring seems to be helpful with regards to specific phobias. Ongoing relaxation training and various meditation techniques also appear to have significant results in treating various anxiety disorders. However, there are a number of drawbacks to these available treatment modalities.

Anti-anxiety medications tend to be addictive and have significant side effects and should be prescribed only as a last resort. The amount of intellectual and personal discipline necessary to maintain an ongoing practice of biofeedback, meditation, and relaxation is often lacking in patients who appear in the clinician's office. Individuals

suffering from long-term anxiety and reactive depression often have lost the volition to engage in a long term meditative and relaxation practice that would be helpful to them. An alternative that has been demonstrated to be effective is an alternative health treatment that is cranial electrotherapy stimulation (CES). Cranial electrotherapy stimulation has become well studied in the last 10-15 years as demonstrated by the 100+ research articles that have been written. However the FDA criticized many of the studies as having flaws in the research design that make them necessarily suspect, even though nearly all of the research demonstrates an improvement in anxiety patients who are being treated by CES. In response to the FDA's previous critique of research, a triple blind experimental design was established to test the effectiveness of a single treatment of CES on a population of anxiety ridden patients and patients whose anxiety has resulted in acting out behavior that has caused legal problems, specifically substance abuse and aggravated sexual assault.

The individuals drawn from our general psychiatric population suffered from a clinically significant anxiety dysfunction, as classified by the DSM IV, including agoraphobia, generalized anxiety disorder, with and without panic attacks, obsessive-compulsive disorder, asocial phobia, and simple phobia. Also, two of these individuals suffer from manic depressive disorders but they were included in the study because they reported stressful and anxious situations as being the responsible trigger to their manic episodes.

Review of Literature

A review of the literature investigating cranial electrotherapy stimulation (CES) discovered a large amount of research, much of which was favorable to CES as a treatment modality. Several studies have demonstrated the effectiveness of CES in clinical depression (Briones 1973; Flemenbaum 1974; Hearst 1974; and Phillip 1991). In the early days of CES, it was used as a means of assisting individuals to overcome insomnia. Those

studies were less remarkable because of what appeared to be a confusion between sleep disorder as a symptom of depression and anxiety in comparison to simple insomnia (Frankel 1973; Moore 1975). CES does not appear to be helpful in cases of simple insomnia. However, in studies investigating the triple symptoms of insomnia, depression, and anxiety, several studies have demonstrated successful intervention with CES (McKenzie 1971, 1974; Magora 1967; Levitt 1975; and Rosenthal 1970, 1972).

The effectiveness of CES for substance abuse treatment has also been demonstrated in recent studies (Bianco 1994; Gomez 1979; Krupitsky 1991; Overcash 1989; Smith 1992; and Wiengarten 1981). There appears to be no reported ongoing use of CES in any standard inpatient or outpatient facility for substance abuse, which is remarkable given the research.

CES research has also demonstrated the effectiveness of CES treatment with HIV patients with T-cell counts less than 400, to help them cope with stress. As a result of lower stress, there has been evidence of an increase in T-cell replication Schummer (1995). However, it would be premature to state that CES is an effective means of boosting or assisting T-cell replication.

Other studies demonstrate that CES has successful application in the area of spinal cord injuries (Wharton 1982); closed head injuries (Smith 1994); asthmatic children (Magora 1967), and, attention deficit disorder-ADD (Smith 1993). While these studies are exciting as new areas of research, it would be premature to suggest that CES would be a treatment of choice until further research is done.

In the area of anxiety and phobia, CES demonstrates its greatest usefulness. Hefferman (1995) demonstrated that one treatment of CES reduced the anxiety symptoms in his patients who were unresponsive to medication and the effect was demonstrated to be carried over a week later on a retest. Smith (1994) reduced discomfort of long term phobic patients suffering an average of 16.3 years from severe phobic reactions with one treatment. Passini (1976) found significant reduction in anxiety symptoms of inpatient

subjects. Even specific anxiety related to dental work was shown to be reduced (Hochman 1988) using electrostimulation devices.

Two different meta-analyses of CES were done. O'Conner, et al. (1991) investigated the effects of CES for primary and secondary symptoms related to substance abuse. It was this study's conclusion that CES was useful for withdrawal symptoms related to substance abuse. Klawansky (1995) and his associates at harvard concluded that CES was significantly effective over sham treatment groups for the treatment of anxiety in 7 of the 8 studies that used continuous measurement scales.

The review of the literature demonstrates a clear indication of the value of CES. In the Federal Register of August 1995, the FDA asked for a premarketing approval for CES devices. In reviewing the literature they found flaws in some of the studies to date, and hence the need for further research following strict FDA guidelines to test the effectiveness of the CES technology in the area of anxiety control.

Purpose

The purpose of this study is to test the effectiveness of cranial electrotherapy stimulation on anxiety and stress, as reported by the State Trait Anxiety Inventory (STAI), EMG, and skin temperature (ST). CES was administered by the *Alpha Stim 100* which creates a bipolar dc modified square wave with a net dc of 0, using 300 microampes at 0.5 Hz for 20 minutes.

The subjects were selected from the general population of the Delos Mind / Body Institute. Subjects reporting anxiety or inordinate amounts of stress during their intake interview were selected as participants in this study. These subjects fell into two primary groups, probation clients and general population patients. The probation clients were further subdivided into two groups including impulse control disorders usually related to alcohol and or substance abuse, and individuals suffering from a history of sexual impassivity (pedophilia). The original number of subjects selected for this study was 140

but due to the inability of several of the subjects to read and write in either English or in Spanish, the final number in this study included 105 subjects.

Treatment Method

Subjects were treated with Alpha-Stim for 20 minutes during their regular therapy group. The therapy groups were divided into three experimental populations: 1) group A: individuals receiving active treatment; 2) group B: individuals receiving placebo; and 3) group C: individuals receiving no treatment (control). The subjects were randomized, based on which seats they took in the group therapy room. Prior to the individuals entering the room each seat had been assigned a treatment. Using a doubleblinding box, the researcher was unaware at the initial hookup as to which subject was receiving which treatment. The control obviously was known because no hookup was done.

Over a period of ten days, all of the various Delos groups that worked with stress and or anxiety were tested. All subjects were tested using the dependent variables of STAI, EMG, and ST, before and again immediately following the treatment condition. The STAI exam was issued first, followed by EMG on the frontalis muscle and then skin temperature recorded in a hand held temperature probe. All three dependent variables were administered again post treatment by a student resident.

Each condition was recorded on the primary tabulation sheet , recording the connection jack from the blinding box, or control if subject was not wired to any device. Tabulations were done based on blinding box number and control. Upon the completion of all 107 subjects, the manufacturer of the blinding box was called and he informed the researcher of the treatment condition of the four possible numbers used on the blinding box. Those conditions were then compiled by number and sent to Southwest Medical School Bioresearch Center for tabulation and comparisons using statistical norms designed by their department. Information presented to the Bioresearch Center was presented blind with no indications as to what treatment condition each of the subjects was submitted.

As mentioned earlier, stress and anxiety were operationally defined on the three separate dependent variables. The scores on the STAI between 40 and 70 were accepted. Scores between 75 and 95 were accepted on the skin temperature (ST) and the scores higher than 4.0 were accepted on EMG. These scores were permitted only pre-test, with no obvious restriction on post-test scores.

Instrumentation

The *State/Trait Anxiety Inventory* (STAI) is an instrument consisting of 20 questions in both state and trait anxiety which was designed by Charles Spielberger in the early 1970's. This instrument has been used in more than 2000 studies according to the instrument manual. By the year 1989 there has been 3,300 studies and reviews of this instrument for the reliability and validity of anxiety. For this research project, only the state anxiety questions were used.

The *EMG* is a time tested technology in the area of anxiety, which measures the voltage differentials across subcutaneous tissue. The particular device that was used for this study was the NM-100 EMG Scanner produced by Noromed. This particular device been used in many research projects.

The *Skin-Temp (SK)* was measured by the *Stress Computer*, which is distributed by the Conscious Living Foundation. It consists of a temp-probe that is either held or attached to the skin of the subject. In this case the probe was held between the thumb and forefinger of the dominant hand.

The CES unit was the *Alpha-Stim 100* which was described earlier in this section. Ear clips were attached to the right and left ear lobes of the subject and 0.5Hz was administered at 300 microamperes for 20 minutes. Electromedical Products International, Inc.

Report of Data

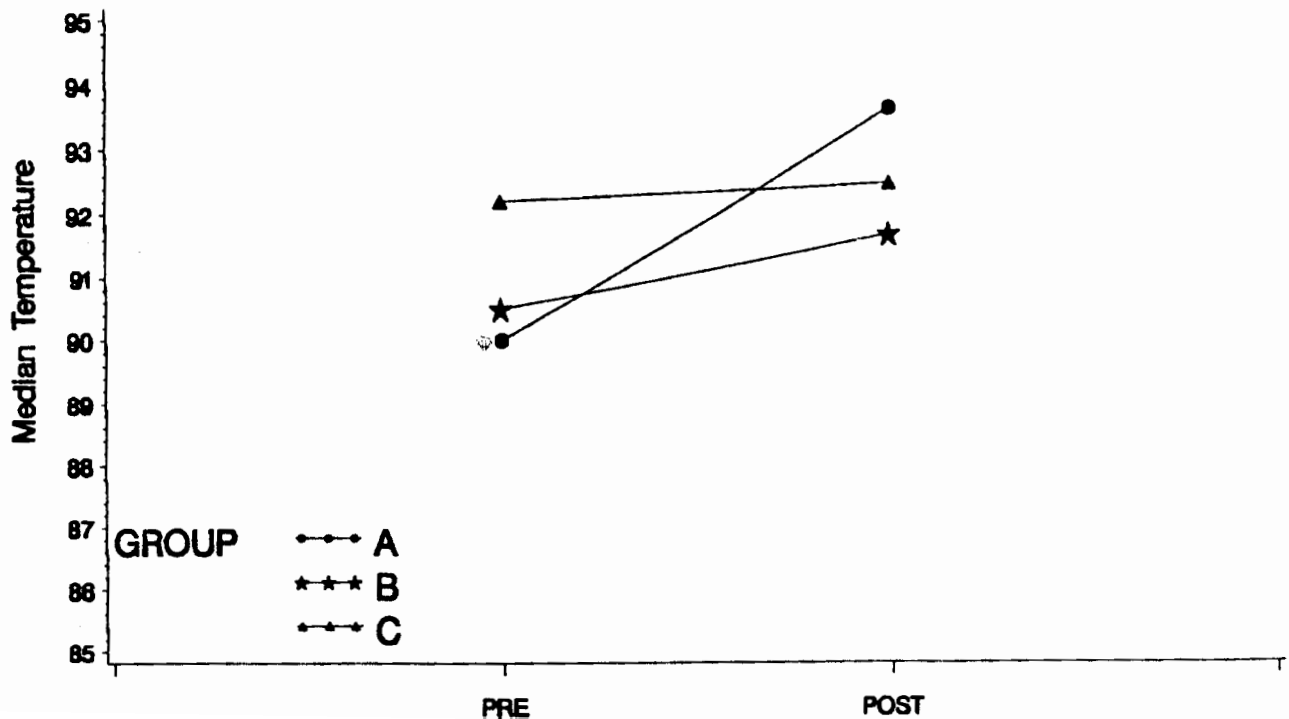
The following tables and graphs report the various results of the research. The interpretation of data is as follows: "A" refers to treatment group; "B" refers to placebo group; and, "C" refers to control group. The statistical data used the median rather than the mean for analysis to eliminate scores that fell widely out of range and would have skewed the data interpretation.

TOTAL GROUP REPORT FOR TEMPERATURE

group	n	pre-median	pre-std	post-median	post-std
A	38	90.0	5.62581	93.60	3.35781
B	30	90.5	4.89908	91.65	4.80665
C	24	92.2	5.58593	92.45	5.88956

p for: A vs B = .0141; A vs C = .0011; B vs C = .3109
significance is noted!

PRE AND POST MEDIAN TEMPERATURE BY GROUP



Report of Data

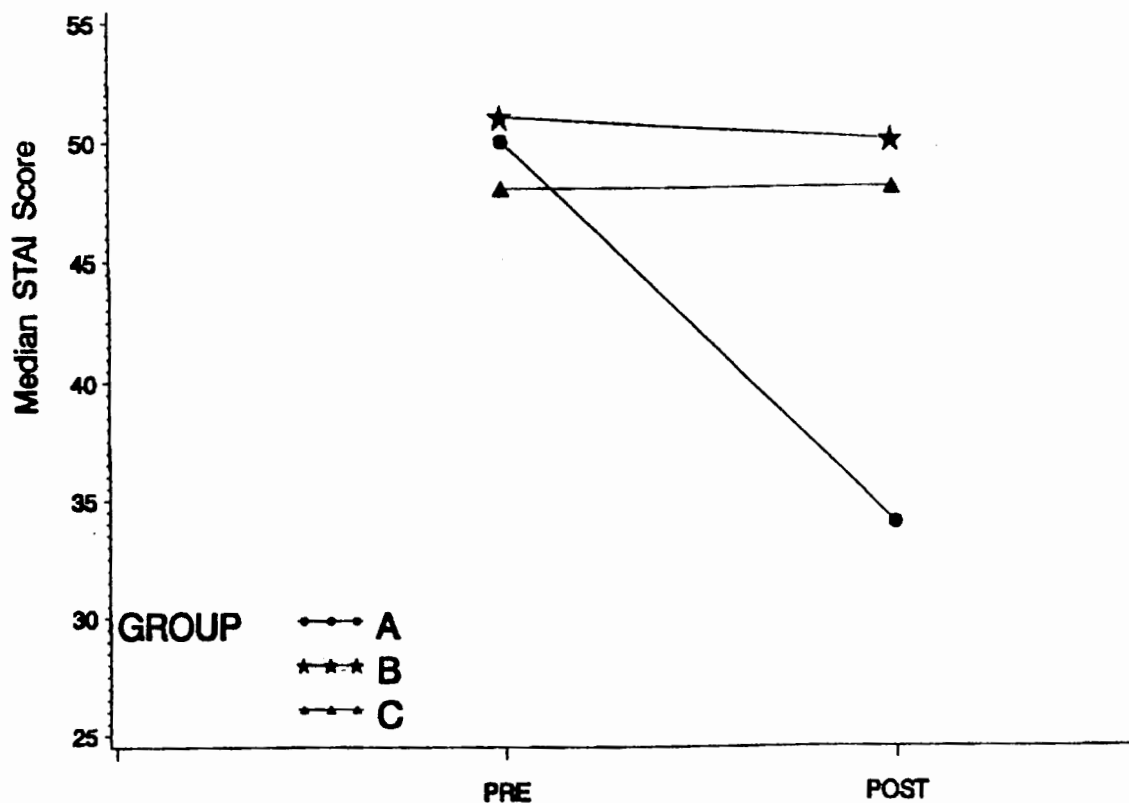
The following graph and chart are based on the Median scores.

TOTAL GROUP REPORT FOR STATE/TRAIT ANXIETY INVENTORY

Group	N	Pre-Med	Pre-Std	Post-Med	Post-Std
A	31	50	8.12285	34	7.38845
B	14	51	8.58312	50	8.45967
C	15	48	5.96418	48	8.80638

p for: A vs B = .0001; A vs C = .0001; B vs C = .3902
 significance is noted!

PRE AND POST MEDIAN STAI SCORES BY GROUP



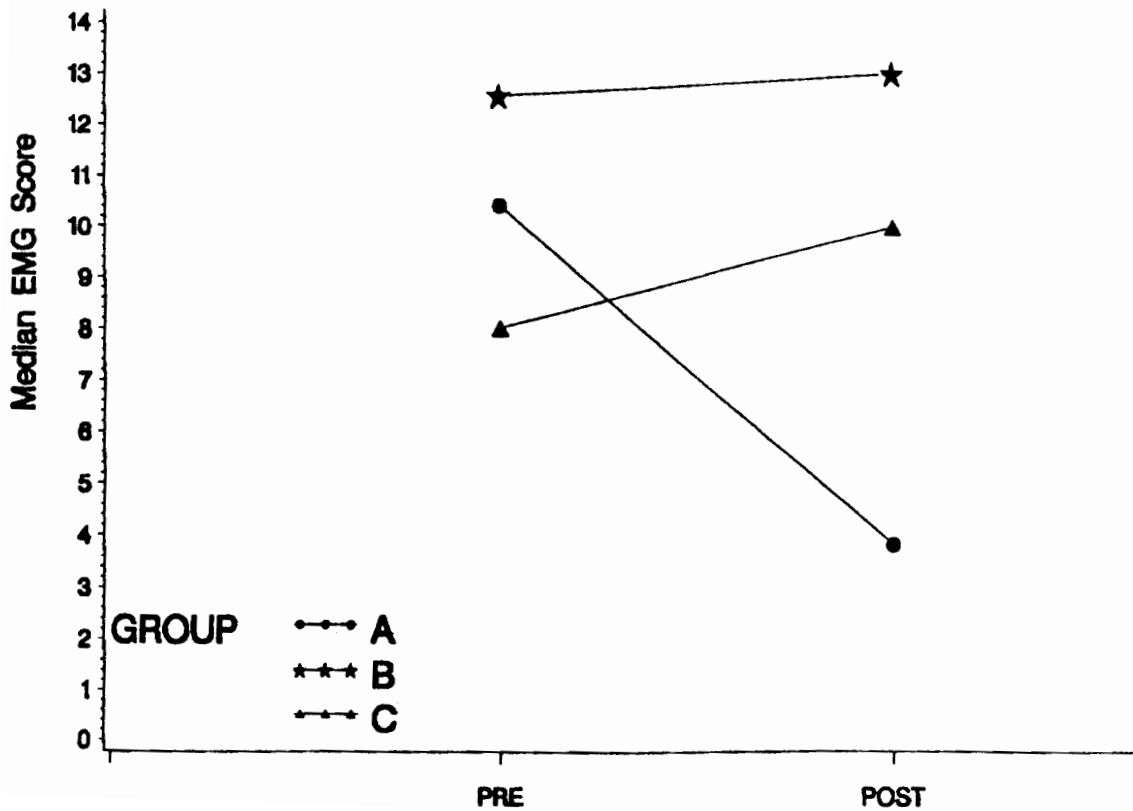
Report of Data

TOTAL GROUP SCORE FOR EMG

Group	N	Pre-Med	Pre-Std	Post-Med	Post-Med
A	27	10.40	7.1227	3.80	4.9774
B	16	12.55	10.4547	12.95	10.6505
C	19	8.00	9.1110	9.95	9.6866

p for: A vs B = .0001; A vs C = .0001; B vs C = .6693
 significance is noted!

PRE AND POST MEDIAN EMG SCORES BY GROUP



Report of subdivided data

Because of such high significance numbers, the decision was made to further analysis the data within various groups. The two main groups were psychiatric patients and probation clients. The following tables and charts were obtained.

Psychiatric Subjects (post - pre score differences)

Variable	Group	Median	Std	p: A-B	A-C	B-C
EMG	A	-4.2	5.47	.0005	.0013	.2888
	B	-0.4	1.67			
	C	-1.6	2.63			
STAI	A	-20.0	11.64	.0001	.0003	.7217
	B	-2.5	3.83			
	C	-1.5	.08			
TEMP	A	3.2	4.28	.0231	.0036	.3735
	B	1.2	4.76			
	C	0.4	2.21			

Groups B and C are not different with regards to the change from pre to post for any variable. However, A and C are significantly different for all variables while groups A and B are different for EMG and STAI but not for TEMP (using the $.0167$ cut off for significant difference $.05/3 = .0176$)

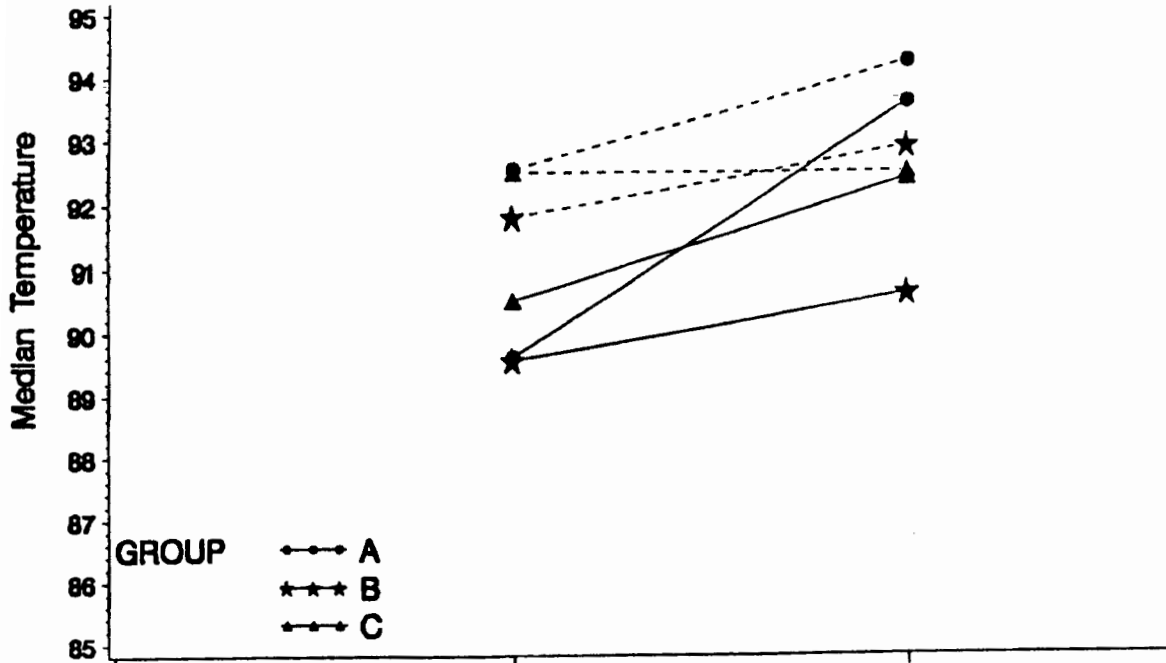
Probation Subjects (difference post - pre)

Variable	Group	Median	Std	P value: A vs B	A vs C	B vs C
EMG	A	-3.0	7.02		.0505	.0560
	B	-0.2	2.56			.8203
	C	0.0	2.00			
STAI	A	-12.0	5.90		.0330	.0078
	B	-2.5	4.55			.2931
	C	0.0	5.87			
TEMP	A	3.2	3.74		.3386	.1688
	B	.01	2.17			.4809
	C	.03	2.38			

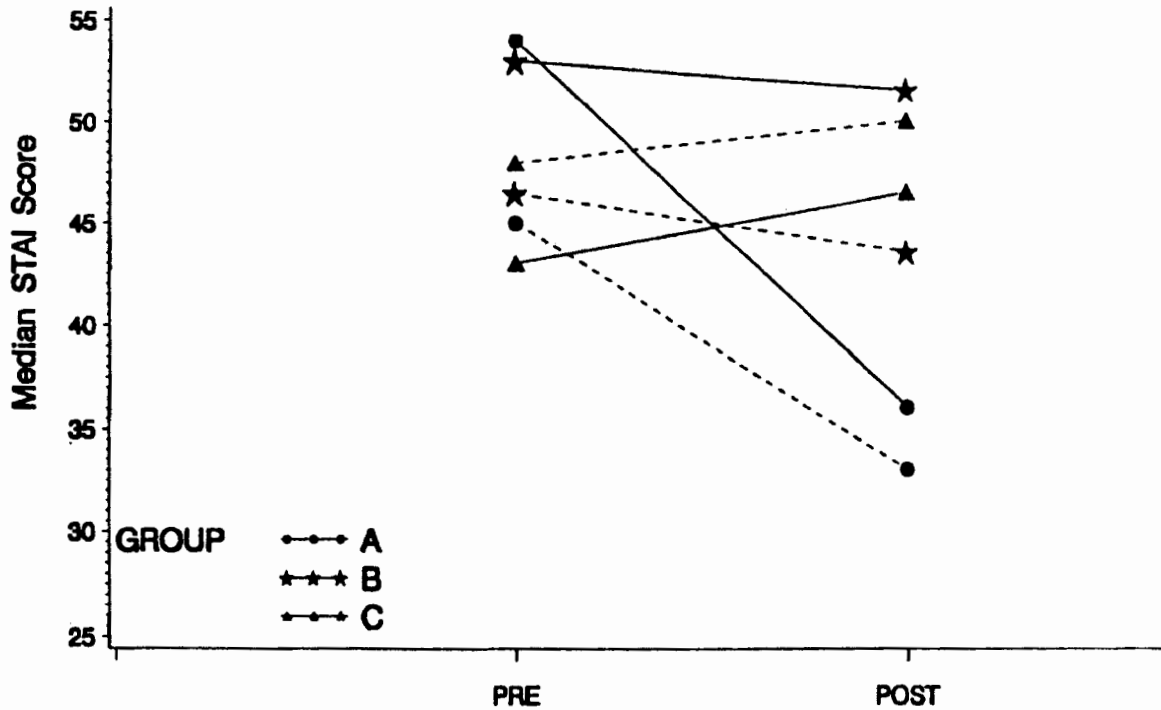
The B and C groups are not different for any variable. Groups A and C are significantly different for STAI only, however the trend is clearly noted for significance among the probation subjects receiving treatment.

The following graphs represent these changes.

PRE AND POST MEDIAN TEMPERATURE BY GROUP

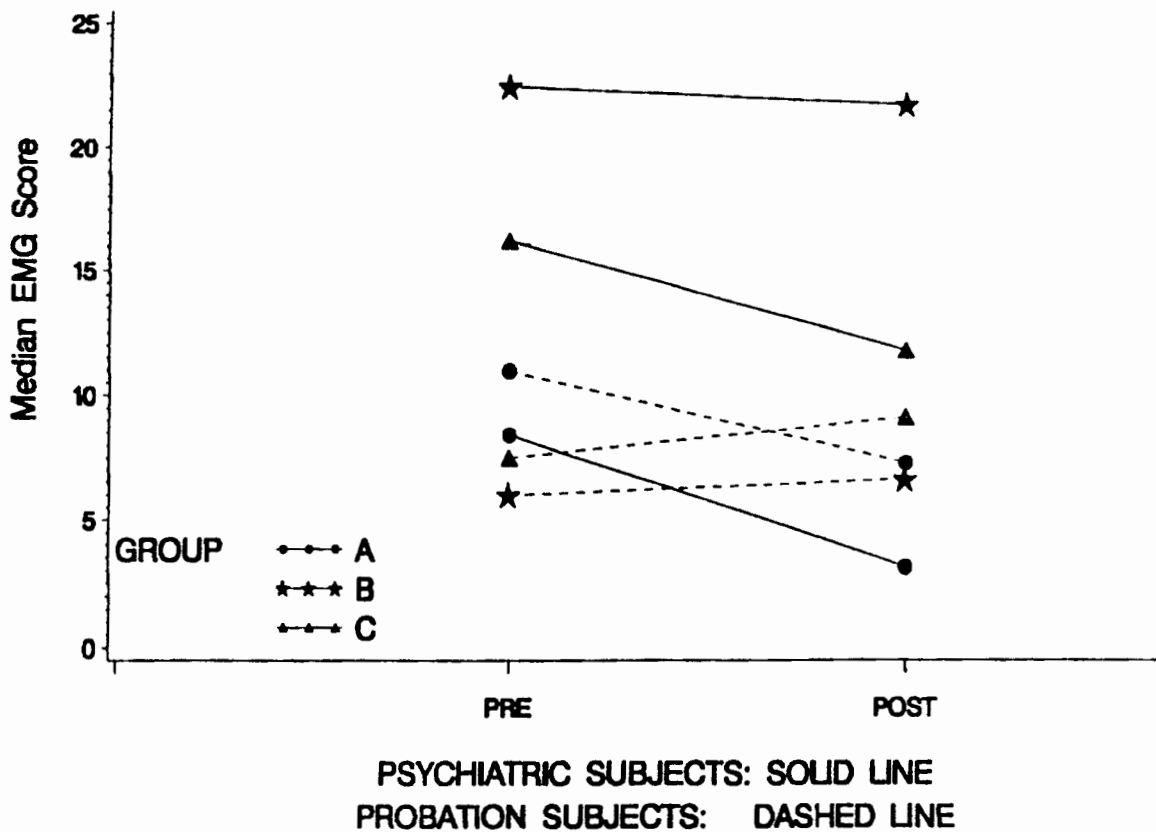


PRE AND POST MEDIAN STAI SCORES BY GROUP



PSYCHIATRIC SUBJECTS: SOLID LINE
 PROBATION SUBJECTS: DASHED LINE

PRE AND POST MEDIAN EMG SCORES BY GROUP



While the trend between both psychiatric and probation subjects remains constant in the direction of significant difference between CES treatment across all conditions, the psychiatric subjects as a group are more responsive to the CES treatment with better results when they received treatment. Several factors may influence these results. Psychiatric subjects are voluntarily in treatment with an acute awareness of psychological pain. Probation subjects are court-ordered into treatment with a great deal of resistance and denial, and with little or no motivation for change. The fact that change occurred in the probation subjects in spite of the resistance and denial speaks well of the efficacy of CES. It is also important to note that the probation subjects began as a group reporting less stress than the psychiatric subjects. One area of research would be to investigate only probation clients and account for their resistance and denial in the design of the experiment.

Results and Discussion

The differences between the pre-treatment and post-treatment groups are clearly demonstrated. There is significant difference on the scores across all variables for Group A which received treatment. The p value significance was as high as .0001 in some instances and always less than .02 in all instances when compared between Group A and both other groups. The reason that the total N appears less than 105 is because of the need to eliminate statistically individuals who did not meet the anxiety criteria based on the pre-treatment scores.

Group A consisted of general psychiatric patients who reported various psychological conditions ranging from manic-depression to psychosis and including major depression, all of which demonstrated significant anxiety. The treatment was effective regardless of the diagnosed Axis I condition and Axis II situation. The statistical data provided clarifies any and all questions regarding the efficaciousness of CES. But the comments following the treatment by the patients are also telling.

Several patients asked to return for the next several days for further treatments because it was the first time that they have felt relief from their symptoms completely. We complied with their requests, but did not continue the research because we had limited the research to a single treatment protocol.

Of important interest was the fact that word-of-mouth referrals has doubled over the two weeks following the experiment. Those who received treatment have mentioned it to other patients who suffered from similar conditions, but who were being treated in other centers, and those patients have been calling and asking if they can volunteer for further research. In the history of Delos Mind/Body Institute, it is the first time we have had to turn away volunteers for an experimental treatment.

When we began the research project, several members of the team, including this researcher, had significant doubts as to the effectiveness of this technology that was reported in the literature. In addition, the concerns of the FDA caused further concern and suspicion regarding this technology. But after this project, we are completely convinced as to the value of this treatment methodology for many of our patients.

With the above said, some cautions need to be added. In working with reactively depressed and anxious patients, the value of the human relationship cannot be understated. We would see this new technology as an adjunct to the treatment protocol for anxiously depressed patients, rather than as the first line of treatment. There is perhaps the danger that clinicians reading this report would be tempted to use CES as the only step in treatment for the patients, in a manner similar to many psychiatrists who merely script medication without psychotherapeutic intervention. Because of the power of this technology, there would also be the temptation by managed care companies that are profit driven to view this technology as a means of substituting CES for the human therapeutic interaction with the patient. There is nothing to support or encourage such a move.

The power of this technology is obvious, but it does not address the etiology or phenomenology of the pathology. The best treatment possibilities of CES might be to use the technology immediately prior to the psychotherapy session or even during the session. Further research is essential to explore the correct place of CES in the full treatment protocol of reactive depression and anxiety.

Another area that would need further investigation would include trait anxiety. The STAI demonstrated an almost immediate improvement for state anxiety. However, individuals who suffer from a chronic pattern of anxiety responses would be diagnosed as trait anxiety, and there was no aspect of this experiment that addressed that level of concern. It would be reasonable to hypothesize that continued reduction in state anxiety, coupled with either cognitive-behavioral or interpersonal relational therapy would be

effective in reduction of trait anxiety. Several of the studies have suggested that possibility, but no long term longitudinal studies have been done investigating personality styles.

One subject who had been trained in meditation and hatha yoga, reported a similarity between the phenomena of those relaxation exercises and the experience of CES. A tremendous amount of research has been done in the areas of relaxation response, biofeedback, Transcendental Meditation, yoga, breath response and centering. That research generally indicates a favorable response to those various techniques. Another area of study would involve a repetition of those studies using CES and comparing the results. Since CES appears to induce an alpha state in the subjects, the similarities between various meditators and CES is obvious.

Any condition that might be improved by relaxation and stress reduction would appear to be grist for research involving CES. The neurophysiological mechanisms that CES manipulates are unclear at the present time and further research is definitely encouraged to understand those mechanisms, similarities between the relaxation response and CES outcomes would suggest investigation of the hypothalamic limbic system.

Unexpected Results

This researcher was surprised by two unexpected results in the testing data. As is obvious from the charts, the placebo group actually showed a decrease in temperature rather than remaining the same or going up. This would suggest that the placebo group was demonstrating some degree of stress in the process of sitting and receiving placebo treatment but without results. This would perhaps speak to the expectation of the placebo group. The control group would have no expectations in the change in sensation since they were not wired to any device. The active treatment group obviously demonstrated a much more relaxed countenance as they sat waiting for the full treatment process to be completed. Therefore, the B group increase in skin temperature could reflect a form of

anxiety because they were expecting something that did not happen. The result was unexpected in the research.

Another unexpected result was among the psychiatric patients. A large number of them ended up in treatment chairs as compared to other subjects. In the data, 75-80% of the psychiatric patients appear to have chosen an active treatment chair which cannot be explained simply by chance. In examining the situation of the room, what we have discovered in the A,B,C arrangement of the chairs is that the vast majority of treatment chairs were located near doors and windows in the group room. What we noticed in the treatment process is that the psychiatric patient would usually enter the group room first with probation clients having to be encouraged a second or third time into the room. The compliance of the psychiatric patient gave first access to the chairs and they tended to choose the chairs closest to the doors and windows whereas, probation clients would tend to fill in the remainder of the chairs. The significance of this has been addressed by using a non parametric man-whitney test with the bonferroni correlation to adjust for this unequal distribution. Even so, among the psychiatric population, there is still a significance of .01 across EMG and STAI dependent variables with marginal significance demonstrated with the skin temperature response. The randomization of the chairs was done but could not account for human behavior patterns differing from psychiatric patients and court mandated patients. To avoid this discrepancy in the future, it would be of value to randomly assign conditions by lottery rather than randomizing by a selfselective process.

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