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# The use of cranial electrotherapy stimulation in the treatment of closed-head-injured patients

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This double-blind study sought to discover if cranial electrotherapy stimulation (CES), which is a known treatment of depression, anxiety and insomnia in non-head-injured patients, could be an effective, drug-free treatment of stress-related symptoms in the closed-head-injured (CHI) patient. In this study 10 CHI patients treated for 45 min daily, 4 days a week for 3 weeks, responded significantly on all negative mood factors of the Profile Of Mood States, while five sham-treated and six placebo controls did not. While the majority of the patients were known seizure cases, no patient suffered a seizure during CES therapy. No placebo effects were found, nor were any negative effects from CES treatment seen.

## Introduction

Cranial electrotherapy stimulation (CES) is a known treatment for the alleviation of anxiety, depression and insomnia, and has been successfully used to treat these disorders in patients in a wide variety of patient groups [1]. From the results of both human [2, 3] and animal studies [4, 5] it is theorized that CES may achieve its effects by normalizing neurotransmitter homeostasis in the brain.

Successful initial trials of CES with head-injured patients have recently been reported [6–8]. Closed-head-injured (CHI) patients living in a sheltered housing centre complained of stress-related symptoms of anxiety and depression. Many had problems sleeping all night. The house manager was concerned over the number and amounts of medications many of them were taking to alleviate these problems, and asked whether CES might alleviate some of these symptoms in his residents (personal communication, George Bolden, Manager of Heads Up, Inc., Fort Worth, Texas). Following visits with patients and staff at the residence we decided to do a double-blind study of the effects of CES on CHI patients.

## Methods

Twenty-one CHI Caucasian males, virtually all of the residents of the sheltered living facility, were studied. Their average age was 30 years, the time since injury ranged from 6 months to 32 years (mean = 11 years; SD = 8·91 years). 14 (67%) had been injured in car or motorcycle accidents, while others had been injured by industrial

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gas poisoning, from accidental falls, or from mugging with an iron pipe. One was diagnosed as inoperable cerebral carcinoma. Thirteen (62%) of the subjects admitted to having been under the influence of drugs and/or alcohol at the time of their injury. Nine (43%) had been treated for chemical dependency prior to their injury and five (24%) had joined in this treatment since. Eighteen (86%) of the subjects were known seizure patients, and most of these were on anti-seizure medications during the study.

The list of other medications they were taking was long and involved. Every patient was taking at least three different medications and some were taking five or more, with no two patients on the same medication schedule. We assumed this might have an effect on their response to CES, and determined to cancel (or spread out) any medication effect by randomizing the subjects into our three experimental groups.

Following medical evaluation the patients were given an opportunity to enter the study by signing a consent form. In some cases parents or guardians were also asked for consent, if we were not certain the subject completely understood the experimental procedures outlined to him. Next the Profile Of Mood States (POMS) was administered. The POMS is a standardized paper-and-pencil test that measures the following mood factors: tension/anxiety, depression/dejection, anger/hostility, fatigue/inertia, and confusion/bewilderment. It also has a vigour scale, which is considered non-clinical and was not used. A total mood disturbance score was also obtained.

By drawing names from a hat, patients were assigned to three groups: group I served as placebo controls and continued in their ordinary activities during the study with no access to CES devices. Group II served as sham treatment controls and were placed on CES devices via double-blinding boxes, but received no treatment. Group III were placed on CES devices via double-blinding boxes and received active CES treatment.

For CES treatments we used the CES Labs device. It promised alternating current with no d.c. bias, pulsing 100 times per second on a 20% duty cycle, with a maximum of 1·5 mA output. The devices were plugged into the input side of the double-blinding boxes, each of which had five settings. The first setting always passed current through to the patient, the other four were randomly set so that two would pass current and two would not. These settings were different in each of the boxes, to keep the therapist from learning a setting-treatment pattern.

For treatment, patients in groups II and III were gathered in the residence living room and CES electrodes coming from the output side of the double-blinding boxes were placed on each subject, one behind each ear lobe. The double-blinding boxes were placed on the first setting, allowing current to pass through to each subject. The CES device was then turned on, and the current which was passing through the double-blinding box was elevated by the therapist until the subject signalled that he first felt the stimulation. The therapist then backed the current down until the subject signalled that he no longer felt it. At that point the therapist turned the selection switch on the double-blinding box to a randomly preselected setting, at which time the current continued in some, and was turned off in others. No patient felt the stimulation for more than 2 or 3 s during each session. Neither the patients nor the therapist knew who was receiving treatment. Treatment or sham treatment continued for 45 min, once a day, Monday through Thursday for 3 weeks, or a total of 12 sessions. At the end of that time all patients were again administered the POMS.

Following the second POMS the therapist determined which patients had actual treatment and which had been sham-treated. She divided the POMS scores into three unidentified groups for blind statistical analysis by the statistician.

## Results

Through the vicissitudes of random selection via the double-blinding boxes there were five subjects in group II and 10 in group III. The pretreatment and post-treatment means of the three groups were compared with Fisher *t*-tests. These means are shown in Table 1, where it can be seen that the treatment group improved significantly on every subtest of the POMS while neither of the control groups showed significant improvement on any subtest. Upon comparison of the response of the placebo controls with the sham-treated subjects no placebo effects were found. Therefore the two control groups were combined to illustrate the relative effectiveness of CES treatment in our CHI sample, as shown in Figure 1. These results were obtained in addition to any effects of the psychoactive medication the majority of the subjects were using.

The CES therapist and staff at the centre had been asked to record any seizures that occurred during the study. Only one patient was seen to have a seizure, and it was learned that he was receiving sham treatment. CES stimulation, therefore, was not found to be associated with seizure activity either during the study or later when 3 weeks of regular, above-threshold stimulation CES treatment was made available to all the residents following the study.

## Discussion

We had not studied CHI subjects before, but found them surprisingly similar to alcohol and drug addiction subjects that we have studied, as measured by their response to CES on the POMS [9]. This may be partly due to the relatively large percentage of our CHI sample that had been heavily involved with alcohol or drugs prior to or following their injury. If other CHI groups are similar to our sample, CES should prove to be a potent therapy for their addictions, in that other double-blind studies have shown that CES treatment successfully treats anxiety states found during the

*Table 1. Response on the profile of mood states*

| Mood factor | Placebo controls Mean (S.D.) ($n = 6$) | Sham-treated controls Mean (S.D.) ($n = 5$) | CES-treated Mean (S.D.) ($n = 10$) |
|---|---|---|---|
| Tension/anxiety | | | |
| Pre-test | 12·33 (8·07) | 13·00 (6·21) | 12·33 (7·36) |
| Post-test | 12·50 (5·86) | 14·36 (8·25) | 8·78* (5·09) |
| Depression/dejection | | | |
| Pre-test | 20·00 (14·45) | 20·91 (17·79) | 17·11 (12·35) |
| Post-test | 16·17 (9·48) | 18·18 (12·47) | 12·06* (8·71) |
| Anger/hostility | | | |
| Pre-test | 14·83 (11·50) | 16·73 (8·27) | 13·67 (11·20) |
| Post-test | 14·83 (6·18) | 17·55 (12·22) | 10·39* (7·49) |
| Fatigue/inertia | | | |
| Pre-test | 8·17 (7·41) | 9·46 (7·83) | 7·44 (6·75) |
| Post-test | 6·50 (5·82) | 8·09 (6·63) | 5·33* (3·96) |
| Confusion/bewilderment | | | |
| Pre-test | 9·67 (6·15) | 10·55 (5·84) | 8·50 (6·75) |
| Post-test | 10·50 (5·01) | 10·27 (5·10) | 6·22* (3·96) |
| Total mood disturbance | | | |
| Pre-test | 47·83 (43·25) | 52·73 (41·95) | 45·11 (41·95) |
| Post-test | 45·67 (24·16) | 52·33 (36·64) | 31·89* (23·84) |

*Significantly different pre- to post-test.

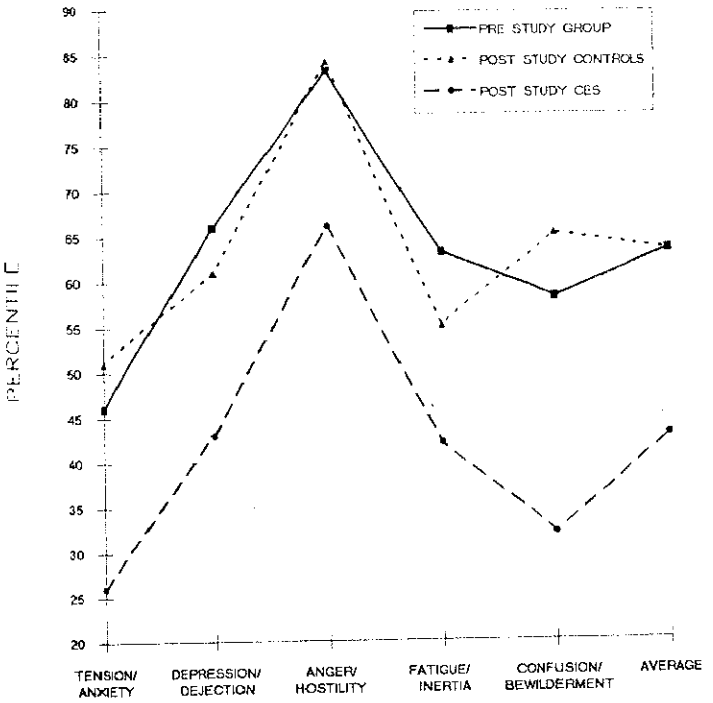


*Figure 1. Patient response to twelve 45-min CES treatments compared with controls.*

alcohol and drug abstinence syndrome and improves their impaired cognitive functioning [10, 11]. In our study anxiety was halved and cognitive confusion dropped by two-thirds on the percentile rankings (see Figure 1).

This limited study suggests that therapists of CHI patients might well try adding CES therapy, a prescription, but non-medication treatment, to the treatment of this currently heavily medicated patient population.

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