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TREATMENT OF MIGRAINE HEADACHE UTILIZING
CEREBRAL ELECTROSTIMULATION

THESIS

Presented to the Graduate Council of the
North Texas State University in Partial
Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE

By

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Denton, Texas

December, 1976

211

England, Ronald R., Treatment of Migraine Headache Utilizing Cerebral Electrostimulation. Master of Science (Clinical Psychology), December, 1976, 38 pp., 3 figures, references, 51 titles.

Cerebral electrostimulation (CES) as a treatment for migraine headache was investigated. Eighteen participants recorded data on headaches for two baseline weeks. Six were assigned to each of three groups--an active treatment group receiving CES, a placebo group receiving a simulated version of CES, and a no-treatment control group placed on a waiting list during the study. The CES group evidenced a significant reduction in headache duration and intensity relative to the placebo group. The waiting list control group did as well as the CES group. A number of hypotheses were put forth in an attempt to account for the unexpected finding.

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TREATMENT OF MIGRAINE HEADACHE UTILIZING CEREBRAL ELECTROSTIMULATION

Treatment of migraine headache can begin only after consideration of the diverse and complex symptoms involved in its diagnosis. Irritability, photophobia, blurred vision, nausea, vomiting, giddiness, flushing, or paling are frequently associated with migraine. Perspiration, tics, tremors, paresis, paresthesiae, speech and mood disorders may also be present. Graham and Wolff (1938) suggested that the hypothalamus could profoundly influence autonomic control of the peripheral vasculature. They postulated that a periodic central disturbance of hypothalamic activity or labile threshold accounted for the periodic migraine attacks. This provided a mechanism whereby emotional disturbances would be mediated from the limbic system to the hypothalamus. Ray and Wolff (1940) discovered that pain from the migraine is transmitted to consciousness by way of the fifth, ninth, and tenth cranial nerves and the upper three cervical nerves. The discomfort associated with migraine is experienced as "an aching, throbbing unilateral pain often coincident with the pulse beat" (Bakal, 1975, p. 370).

The overwhelming majority of migraine patients exhibit common personality features. This personality pattern of constant tension sets the stage for frequent migraine attacks. Goodell (1967) noted personality features common in migraine headache sufferers. These included feelings of insecurity and tension manifested chiefly as "inflexibility, conscientiousness, meticulousness, ambition and perfectionism with inevitable frustration, anger and resentment" (p. 159). He also revealed a hereditary characteristic of migraine and stated:

The inheritance of the trait is through a recessive gene with a penetrance of approximately 70%. Migraine headache commonly occurs when hereditarily susceptible persons attempt to control feelings of anxiety and resentment by means of organized and intense activity. Headache is thus a cranial vascular consequence of a way of life. (p. 160)

Definite conclusions can be drawn concerning familial incidence of migraine headache. In one of the earliest studies, Allan (1928) found a history of migraine in one or both parents in 349 of 382 migrainous patients (91.4%). Goodell, Lewontin, and Wolff (1954) also examined incidence of migraine in the relatives of 119 migrainous patients. Approximately 84% of the patients had at least one relative with migraine. Of the children having one parent with

migraine, 44.2% had migraine; of the children both of whose parents were affected, 69.2% had migraine headache. Lennox (1960) reported data on five monozygotic twin pairs with migraine. In each pair, both twins were affected. Refsum (1968) reviewed several studies and reported migraine concordance rates of 60 to 100% for monozygotic twins and 10 to 40% for dizygotic twins. He also cited several studies reporting female-male ratios from 1.7:1 to 4.0:1 based on populations seeking clinical intervention.

Even though some 3 to 12% of the general population are affected by migraine headache, there has been no clear delineation of etiological basis of treatment. Thus far, the area of headaches has not been of great interest to the psychologist. Bakal (1975) stated:

The apparent lack of interest phenomena reflects a belief on the part of the behavioral scientists that headache has a physical etiology and is therefore not amenable to the psychological study. Paradoxically, medical scientists tend to believe that the majority of headaches do not result from an organic pathology, but rather are the result of stressful situations in combination with predisposing psychological and physiological characteristics. (p. 369)

Treatment modalities for migraine headaches consist of primarily three approaches. Chemotherapy offers varying

degrees of effectiveness and can be accompanied by severe side effects such as nausea and vomiting. Psychophysiological approaches have attempted to modify the migraine patient's physiological responses such as muscle tension and hand temperature through the utilization of such techniques as biofeedback training. Some of the more encouraging results have surfaced in this area. A third manner of treatment which falls comfortably into neither of the aforementioned methods is that of cerebral electrostimulation or CES. Although designated by the Food and Drug Administration as a prescription device, it involves no ingestion of chemicals, nor any active participation on the patient's behalf as is required in biofeedback.

Early studies examining the effectiveness of using medication in the treatment of migraines revealed that the action of Ergotomine when taken regularly and then stopped can produce a rebound headache which closely resembles a migraine attack (Friedman, Brazil, & Von Storch, 1955; Peters & Horton, 1951). Tolerance to Ergotomine can develop when taken regularly. This can result in abuse by exceeding maximum dosage. Friedman and Elkind (1963) concluded that few drugs used to treat migraine headaches were more effective than a placebo. Methysergide, although frequently prescribed for migraine, has little or no value as it produces significant side effects. Some migraine

medications paradoxically tend to increase or provoke nervous tension, myogenic headaches, and even the number of migraine attacks.

Some behavioral scientists feel that the migraine may be more effectively treated if considered a psychophysiological disorder rather than a purely physical phenomenon. Malmo, Shagass, and Davis (1951) proposed that in its most extreme form, the tendency of some individuals to respond selectively in one particular autonomic control can be learned with temperature feedback alone and that some psychosomatic reactions are learned and can be modified. Hand-warming as a treatment for migraine headaches had been reported by Schultz and Luthe (1969). They reviewed literature in which biofeedback was combined with autogenic training. They attributed the generally poor results to the insufficient procedures employed. Maslach, Marshall, and Zimbardo (1972) demonstrated that hypnotized subjects could increase hand temperature a maximum of 4° F. in two to four minutes.

In combining temperature feedback and psychotherapy, it is interesting to note that complete symptomatic relief of migraine was achieved prior to significant progress of psychotherapy in a study by Legalo (1973). In another study, hypnosis and auditory feedback have been shown to enable subjects to achieve control of skin-temperature

regulation (Roberts, Kewmand, & MacDonald, 1973). Unfortunately, the variables of hypnosis and biofeedback were confounded in this study which prohibited discerning whether hypnosis was a necessary adjunct to the learning process.

During the spontaneous recovery from a migraine headache, a noticeable flushing in the hands was noted by a research subject and was accompanied by a 10° F. temperature rise in a period of two minutes (Sargent, Green, & Walters, 1973). This promoted the interest in hand-temperature feedback training of migraine sufferers. It was also noted in this same study that some patients with migraine are not helped by any type of medication. For this particular group, hand-temperature feedback training appears to be an especially promising technique. Sargent, Green, and Walters (1973) stated:

In migraine, which seems to be part of a stress-related syndrome, the somatic response is dysfunction of vascular behavior in the head, related to intense sympathetic dysfunction. Vasoconstriction in the hands is a function only of sympathetic activation and vasodilation is one variable indication of decrease of sympathetic outflow. With these concepts in mind, it seems reasonable to hypothesize that autogenic feedback training for handwarming is effective in amelioration

of migraine because patients are learning to 'turn off' excessive sympathetic outflow. (p. 418)

These authors found an 81% improvement with migraine patients after using temperature feedback training. Some subjects in this study suffered from more than one type of headache. This factor along with the small number of subjects prevents any definite conclusion regarding handwarming techniques from this study alone. They concluded that some headache states may require different types of biofeedback training when headache combinations are found in a single individual.

Several combinations of hand-temperature feedback and other techniques have been considered. Peper (1973) reported the success of two patients who used combinations of autogenic training and hand-temperature feedback. Graham (1975) found handwarming technique via hypnosis to be extremely effective in reducing the frequency, intensity, and duration of migraine headaches. Andreychuk and Skriver (1975) showed a greater percentage of improvement using temperature feedback in treating migraine headache than by either alpha training or hypnosis. Johnson and Turin (1975), using an N = 1 design, concluded, ". . . the subject's improvement during the warming condition was a function of feedback control rather than placebo or suggestion effects" (p. 396). They found that migraine

activity increased during the sessions when the subject received training in cooling her hand temperature. This was in spite of the fact that the subject was undergoing what she perceived to be treatment to reduce migraine activity. On the other hand, there was a decrease in headache activity during the handwarming training. Due to the improvement found during the handwarming training, the authors concluded that the improvement was a function of biofeedback training rather than placebo suggestion effect. Roberts, Schuler, Bacon, Zimmerman, and Patterson (1975) and Boudewyns (1976) were also able to train voluntary control of skin temperature.

Budzynski, Stoyva, and Adler (1970) postulated that daily relaxation practice had led to a generally lower anxiety level. Anxiety is accepted as being a key factor preceding the onset of migraine. Lader and Matthews (1971) postulated that the relationship emotional states inevitably evoke increased muscular tension. They felt that in some conditions, such as tension headaches, excessive muscle tension may form the central pathological process. Autogenic feedback training, as defined by Green, Ferguson, Green, and Walters (1970), consists of combining biofeedback training plus autogenic phrases. Both visual and auditory feedback devices may be utilized to show the subject what is happening to bodily functions. The subject uses mental, emotional,

and somatic visualizations of the autogenic phrases in an attempt to influence those functions. Mitchell and Mitchell (1971) have shown that an improvement rate of 71% was possible when using relaxation training. Weinstock (1972) reported on the combination usage of differential skin-temperature feedback, relaxation, electromyograph biofeedback, and psychotherapy. All seven patients, who had suffered previously from tension or migraine headaches, were headache free for several months after treatment.

Blanchard and Young (1974), in a critical review of research on biofeedback training, found electromyograph feedback training to be at present the best experimentally evaluated method in support of biofeedback methods in general. They found the evidence for the treatment of migraine headaches by skin-temperature training to be questionable. Lack of control procedures provide no substantive conclusions on the therapeutic efficacy of skin-temperature training. The suggestive results warrant further investigation of the technique, but at present a reserved acceptance of the technique is appropriate.

Cerebral electrostimulation, commonly referred to as electrosleep, is a relatively new method of treating a variety of chronic somatic and neurotic complaints. CES refers to a technique of inducing a relaxed state or sleep by means of transcranial application of low levels of electric

current (up to 1.5 milliamps). Electrodes are placed externally behind each ear just below the mastoid processes.

CES is by no means a newly discovered technique. By 1914, Rabinovitch had coined the term electrosleep for the therapeutic process (Boblitt, 1969). She described electrosleep therapy as the placing of negative electrodes on the forehead and positive electrodes in the palms of the hands for the purpose of relaxation. The current applied was three-quarters of a milliamp of direct current. The patient usually fell asleep within a few minutes and would normally sleep for approximately one hour. Upon his awakening, he would feel refreshed.

Giljarowski and Liventsev (1958) made a rediscovery of CES by the cranial application of low intensity pulsed current to humans. Their research represented the first time electrosleep was considered a distinct entity separate from previous research combining electronarcosis and electroanesthesia. During the years between 1914 and 1953, research was essentially a process of experimenting with electrode location placement (Lewis, 1966).

Although sleep may accompany CES, it is no longer believed to be the primary effect of the treatment. Tatsuno and Wageneder (1970), as well as Empson (1973), demonstrated that sleep during the session was not necessary for therapeutic success to take place. Cerebral electrostimulation,

as it is also referred to, is actually a better term for the misnomer of "electrosleep." This change had been suggested previously (Koegler, Hicks, & Barger, 1971; Wageneder, 1969).

A large body of information on CES appears outside the United States. Dodge (1967) stated:

The abundance of published Soviet Bloc materials, the size of the research community and the corresponding resources that must be allocated to CES and electroanesthesia research can leave the reader with little doubt as to the seriousness of the effort, the magnitude of which alone merits the attention and critical analysis of the American biomedical community. (p. 63)

Ivanovsky (1969) noted that skepticism or extreme caution with regard to electrosleep is still prevalent in the United States. Obviously, the reason for this has been the lack of readily available, high-quality literature on the subject. This should not deter study of the subject, but rather heighten the prospect of research in this area.

An early study of CES in America (Forster, Post, & Benton, 1963) showed a decrease in tone of spastic musculature of patients with neuromuscular disorders. Boblitt (1969) found definite research outside the laboratories of those firms marketing the device to be meager. Much investigation of the instrument's therapeutic value was conducted

without experimental controls. Boblitt speculated that CES might be no more than an "electronic placebo" without accurate control procedures. Koegler et al. (1971), through a summary of 24 years of clinical use in Russia and Europe, found CES to be a safe treatment which does not harm patients. They also stated that the ease of application and safety make it possible to use in a manner which would save time and money for the patient. Tomsovic and Edwards (1973) reported using CES on patients of an alcoholic ward of a Veteran's Administration Hospital. They found no differences between treatment and placebo conditions. They attributed any therapeutic effects of CES to the suggestive aspects of the treatment situation.

Marshall and Izard (1974) examined the effectiveness of treating depression in a psychiatric setting with CES. Although depression was apparently reduced, no significant differences between treatment and control procedures were found. Most studies on CES have been reported in the form of clinical trials which include: treatment of cardiac pain and neurasthenia (Andreyeva, 1967); hypertonia (Putan, 1967); obliterative disease of the extremities (Roytenburd, 1967); hypertension (Sergeyer, 1967); eczema and neurodermatitis (Turayeva, 1967); endarteriosis and arteriosclerosis (Kazarnovskaya, 1967); and chronic primary insomnia (Frankel, Buchbinder, & Snyder, 1973; Weiss, 1973). Lack

of control procedures prohibits accepting the favorable results from these studies.

Research on CES usage as a whole suggests that the technique is most appropriately applied to somatic complaints. Research using CES to treat migraine headaches has previously been undertaken (Koegler et al., 1971). The authors experimented with a small group of patients who suffered from severe migraine. Two of the four patients who completed the treatment were significantly improved. One was slightly improved, and the other did not improve. Due to the periodicity of migraine, it is difficult to determine the permanence without a longitudinal study. They felt that psychological factors may have been important. An extensive relationship with the therapist was developed as the subjects appeared to be more talkative under conditions of darkness and being in a supine position. In one of the most improved patients, however, the therapist did not remain in the room during treatment. The conclusion the authors set forth was that CES is not a panacea for chronic headaches and that only certain patients will benefit.

It is the hypothesis of the present research that CES will cause a significant reduction of migraine headache states (frequency, duration, and intensity) in an active treatment group. It is further hypothesized that the active treatment group will evidence significantly more headache

reduction than placebo and no-treatment groups which will not differ significantly from one another.

Method

Subjects

The subjects were 18 individuals solicited by means of newspaper ads. They consisted of 6 males and 12 females with a mean age of 37.9 years. The ages ranged from 21 to 62 years. Selection of migraine subjects was based upon validation by telephone questionnaire (Appendix A) and a previous history of migraine headache. A health data form was completed before initial therapy. This information was utilized to determine presence or absence of contraindications to participation in the study (Appendix B). Each subject was required to make a deposit of valuables to encourage completion of the study. Each subject signed a contract (Appendix C) agreeing that valuables would be forfeited if they did not complete the study.

Subjects were matched on the basis of headache intensity during a two-week baseline period. Six subjects were assigned to each of three groups--the active treatment group, the placebo, and the no-treatment control groups.

Apparatus

A 'Neurotone Model 101' (manufactured by NeuroSystems, Inc., Garland, Texas) cerebral electrostimulation unit was utilized with the active and placebo treatment groups.

Headache report sheets (Appendix D) and a release form (Appendix E) were completed by all subjects.

Procedure

Subjects recorded headache data on report sheets for two weeks prior to therapy. All subjects were given the following instructions before any intervention began:

Although contracting with all prospective clients is being undertaken now, we will not be able to give treatment to all subjects initially. Approximately one-third of those subjects that we cannot initially see will be placed on a waiting list. We have no way of knowing who will immediately begin treatment, and who must wait, as we choose the subjects at random. We require that you continue to keep headache data until we are able to begin your treatment. This may initially appear to be a disadvantage, but when the waiting group receives its treatment, we will know much more about successfully treating the migraine, and be better able to tailor the treatment to meet each participant's individual needs.

Subjects assigned to the placebo control and active treatment groups received CES daily (Monday through Friday) for three weeks. Each subject completed sessions of 45-minute duration.

Electrodes were placed behind each ear just below the mastoid processes according to standard operating procedures given in the instruction booklet for the Neurotone 101 unit. The following instructions were given:

As I slowly increase the current, you will begin to feel a tingling sensation from one or both of the electrodes. When you have begun to feel this sensation, please tell me. I will continue to increase the current until it causes slight discomfort, at which time you should tell me to stop. From the readings we receive between these two points, the proper treatment setting for each individual is derived.

For the placebo group, the amplitude was then decreased to a predetermined level of zero. The level remained the same for the duration of the session except for three random bursts of current to the threshold level. Treatment was the same for the active-treatment group except that after the subject reported a slight uncomfortable sensation, the current was decreased until no discomfort was felt and remained at that setting for the entire 45-minute session. Treatment was given any time during the day, preferably before late evening. No special treatment or preparation was necessary. Standard procedures were followed with the unit at the 100 Hz/4 c.p.s. setting. Treatment occurred in a semidark room while the subject remained in a reclined chair. The research

assistant administering the treatment was separated from the subjects by a screen to minimize interpersonal interaction.

Results

A Wilcoxon matched-pairs, signed-ranks test was calculated for the difference scores for each of these variables. Difference scores between the two baseline weeks and treatment weeks two and three were computed for three variables-- headache frequency, intensity, and duration.

The mean group headache frequencies are shown in Figure 1. There is no significant difference in migraine headache frequency between CES treatment and either control group after treatment weeks two or three.

Figure 2 indicates the mean group headache intensity levels. There were no significant differences among the groups after the second week of treatment. However, when both baseline periods were compared to the results of the third week of treatment, the CES active treatment group was found to have significantly lower headache intensity ratings than the placebo control treatment group, $T(6) = 0$, $p < .025$. No significant difference was found between the waiting-list control group and the active CES group.

Individuals within the CES active treatment group had significantly lower headache duration than placebo control subjects when difference scores were compared after the second week of treatment, $T(6) = 1$, $p < .05$. No significant

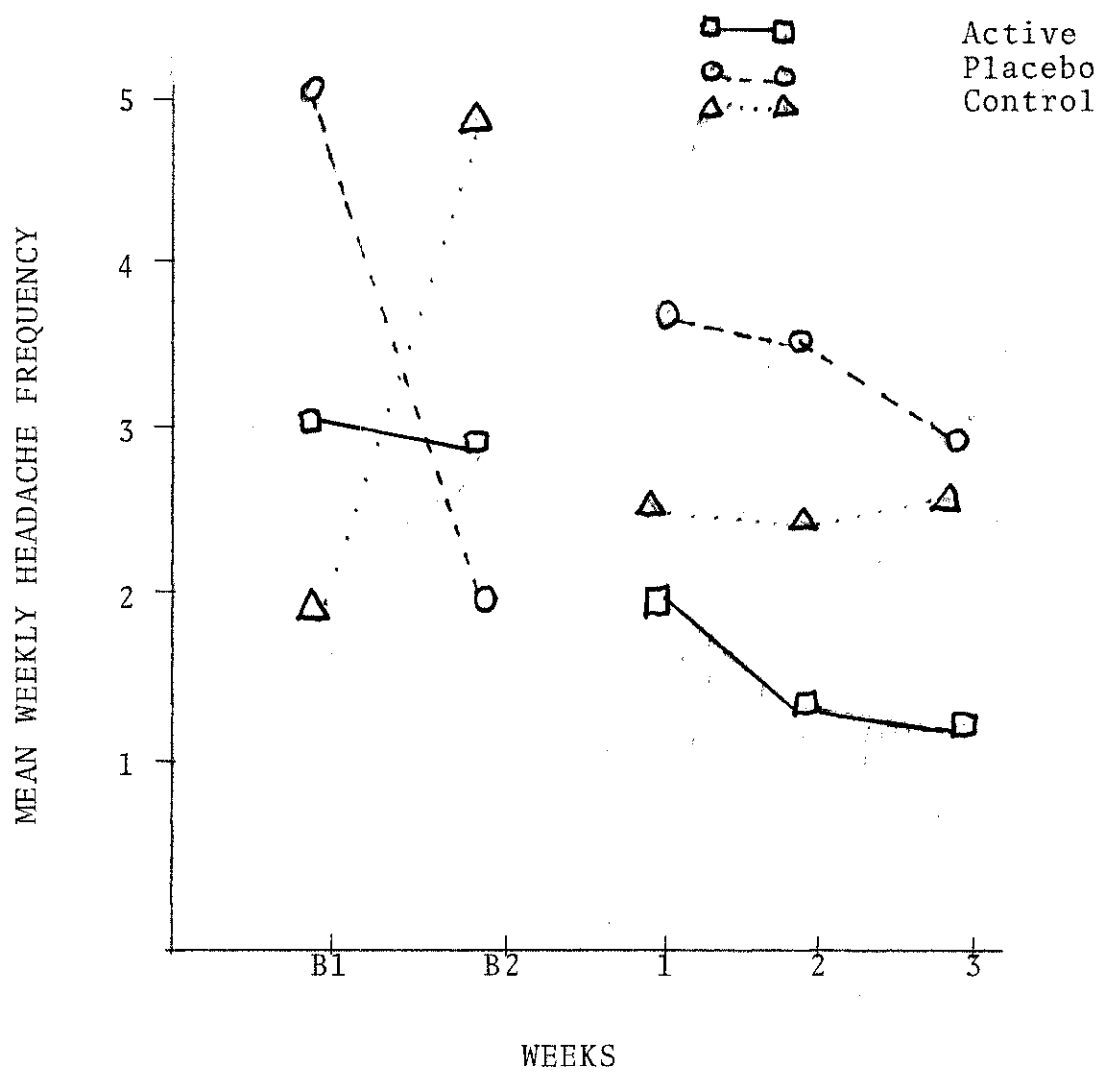


Figure 1. Headache frequency during CES (B1 and B2--baseline weeks, 1 to 3--treatment weeks).

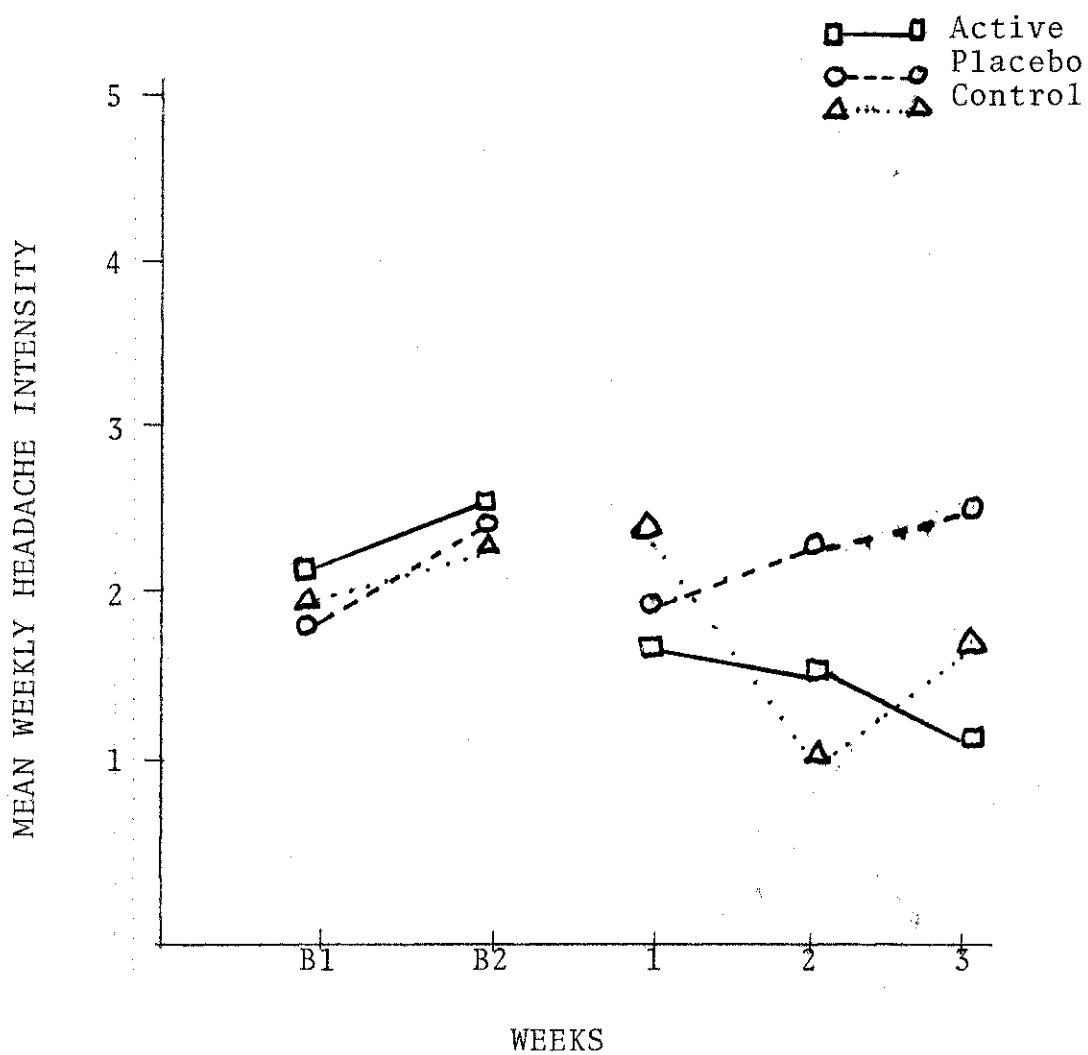


Figure 2. Headache intensity during CES (B1 and B2--baseline weeks, 1 to 3--treatment weeks).

difference was noted after three weeks of treatment. No significance was found when analyzing the difference between waiting-list control and active CES groups during either week of treatment. The mean group headache duration levels are shown in Figure 3.

Discussion

The hypothesis that CES is effective in reduction of migraine headache was supported. On two of the three variables examined, a significant difference was shown between treatment modalities. The variable in which no significance was found was headache frequency. This variable must be interpreted with caution. It is difficult to interpret frequency data due to the fact that frequency may remain constant while a reduction of intensity and duration is occurring. However, as frequency approaches zero, it may be interpreted in a straightforward manner.

A significant difference was noted between the active CES and placebo treatment groups on headache intensity levels after the third week of treatment. However, no difference was found between the waiting-list control and active treatment groups. There are several hypotheses which may account for these unexpected results. It may be that the obtained differences are due solely to chance.

A second rationale is that there were subtle differences in data collection. Subjects within both active and

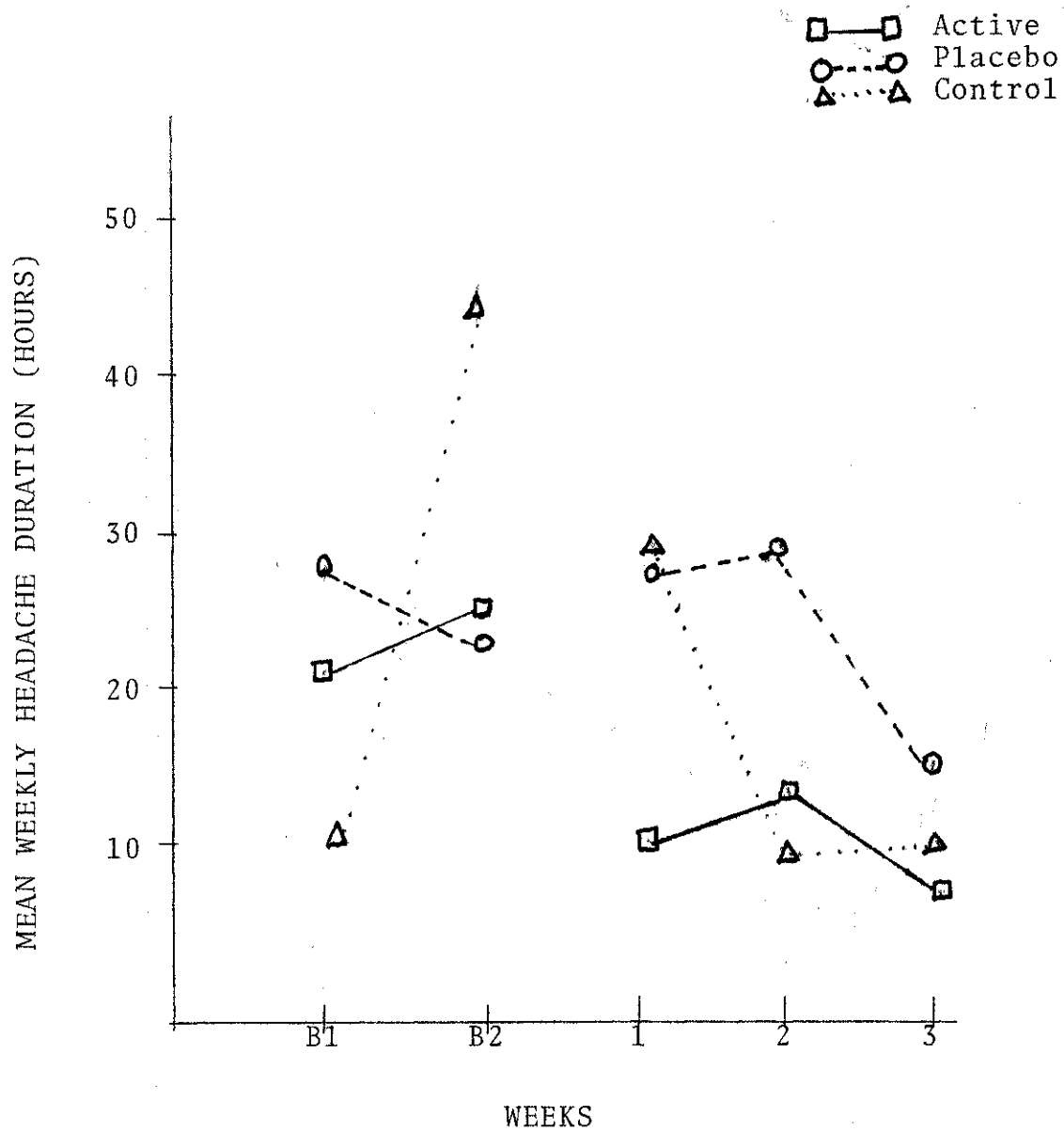


Figure 3. Headache duration during CES (B1 and B2-- baseline weeks, 1 to 3--treatment weeks).

placebo groups received the same amount of contact. They were seen daily. They were instructed to bring their data sheet daily whether it was reviewed or not. On the other hand, the control group was contacted only once a week by telephone. The data which they were recording was duplicated at that time. The fidelity with which the control group recorded data may have diminished when compared with the other two groups. Limited contact may have allowed a distortion of the data collection due to a greater utilization of retrospective recall. Differences in the recording of data should be assessed and/or controlled in further research.

Another rationale which may account for the unexpected results is the effect of being placed on a waiting list. Simply knowing that they are within temporal proximity of relief could result in lowered intensity ratings. That is, being on a waiting list may reduce the cognitive components of environmental stress. Follow-up data would be of assistance in clarifying the overall results.

A similar rationale may account for the generally poor results with placebo treatment. These findings may be due to a similar effect. This effect would be in the opposite direction. Subjects within the placebo group have invested considerable time and effort in their treatment and when improvement is not forthcoming, cognitive dissonance is

created. This dissonance may tend to increase the cognitive components of environmental stress and account to some extent for the trend toward increased headache intensity ratings.

A significant difference was found on headache duration between the active and placebo groups after the second week of treatment had occurred, although it did not hold for the third week. Reasons for the lack of a significant difference between active CES and control subjects have been previously noted in relationship to their effect on headache intensity. Results indicate that there was a reduction of duration level for the placebo group as well as the other groups. This is not consistent with results for the other variables. This may be due to the demand characteristics of the placebo treatment. As placebo treatment subjects near the completion of treatment, there is a demand characteristic for improvement to take place. If this hypothesis is correct, headache duration would be expected to resume during follow-up after treatment terminated.

Several investigators have suggested that the therapeutic changes associated with CES are due solely to a placebo effect (Achte, Kauko, & Seppala, 1968; Boblitt, 1969; Edel, 1970; Frankel et al., 1973; Marshall & Izard, 1974; Tomsovic & Edwards, 1973). Results of this study contradict their hypothesis in that positive verbal reports

were made after each treatment for both active and placebo groups. These reports tend to indicate that placebo subjects believed they were receiving active treatment. Despite this "placebo effect," the general improvement observed in the active CES group was not present in the placebo group. One subject within the placebo group developed a skin irritation at the location of the electrode. She suggested that sensations felt during the treatment were responsible. Many of the placebo subjects reported various continuous sensations during the treatment such as tingling, or buzzing near the electrode, even though electrical stimulation lasted only a few seconds.

Major limitations of this study may be noted as being the small number of subjects and the variable of medication usage tending to confound the results. A larger number would be desirable in further assessment of this treatment technique. Budzynski et al. (1970) suspected medication of disrupting the evaluation of the effectiveness of treatment as it altered pain perception.

Another variable to consider in future research is the possibility that CES could have a differential effect, depending on the type of headache being treated. That is, it may be effective with either migraine or tension headache, but probably not both. Subjects with migraine usually have both, which would tend to confound treatment results.

It would appear that active CES does consistently better than placebo control, which would indicate that CES warrants further research. The waiting-list group in this study confounds what would otherwise be consistent results. Although these results are positive, they are not clear enough to warrant the widespread clinical application of CES until further investigation.

Appendix A

Telephone Questionnaire

Name: Phone:

Age: Occupation: Address:

Headache Symptoms:

Location:

Frequency: Duration:

Circumstances: Time of Day, Certain Recurring Situations,
Seasonal Sensitivity

Intensity of Pain:

Medical Treatment History:

Date M.D. Last Seen:

Diagnosis:

Prescription:

Effectiveness:

of Times M.D. Seen in Last Year:

Medication History:

Types of Medication Taken:

Types Taken Most Regularly:

Current Medication & Dosage Level:

Other Information:

Age Migraines Started:

Age of Highest Frequency:

Age of Lowest Frequency:

Other Health Conditions (Insomnia, Congestion,
Sinus, Heart Problems?):

Family History?

Willingness to keep track of headache incidence on an
hourly, day-to-day basis:

Appendix B

Electrosleep Stimulation Release Form

I, _____, understand the general procedure regarding the use of electrosleep, and am satisfied with the explanation given to me concerning the function and safety of the equipment.

I am currently in reasonably good health, and am not being treated for any medical disorder which would prohibit the use of electrosleep stimulation. Yes _____ No _____

I, the undersigned, agree to hold North Texas State University and/or their authorized representatives harmless from liability for any injuries or damages resulting from the intentional or unintentional injuries or damages resulting from the intentional or unintentional use or misuse and/or negligent use or misuse of any procedures included herein.

I understand that the data collected will be used primarily for my benefit and strict anonymity will be adhered to if the data is utilized for other purposes such as the advancement of knowledge in this area.

Date

Participant

Witness

Appendix C

Electrosleep-Participant Contract

I, _____, do hereby fully agree to participate for the period beginning _____ and ending _____, to record _____ information and to complete a follow-up questionnaire approximately six (6) months after _____. I understand that this project is offered without fee as long as I meet the above requirement. As a promise of my intent to complete this study, I make a deposit of _____ to be kept in safekeeping during my participation and to be returned on _____. If I should not complete this study, said deposit will automatically become the property of the Applied Treatment Unit of North Texas State University.

Date

Witness

Participant

Appendix D

Weekly Headache and Medication Data

	M		T		W		TH		F		S		SU	
HOUR	0-5	MED.	0-5	MED.	0-5	MED.	0-5	MED.	0-5	MED.	0-5	MED.	0-5	MED.
5 am														
6														
7														
8														
9														
10														
11														
12														
1 pm														
2														
3														
4														
5														
6														
7														
8														
9														
10														
11														
12														
1 am														
2														

Headache Intensity Instructions

- S - if you were sleeping
- 0-5 - headache rating if you were awake, where
- 0 - no headache symptoms
- 1 - preheadache symptoms, just barely noticeable
- 2 - preheadache symptoms increased, but able to ignore
- 3 - headache symptoms painful, conscious of presence most of the time, but able to perform any task
- 4 - headache symptoms, severe, concentration difficult
- 5 - headache symptoms incapacitating, intense pain, unable to perform any tasks, bedridden.

Appendix E

Informed Consent Form

I, _____, hereby give consent to _____ to perform or supervise the following investigational procedure or treatment: electrosleep stimulation and the utilization of electronic instruments to monitor physiological responses such as brainwave activity, muscle tension, heart rate, blood pressure, and skin temperature. I understand that it is suggested that this procedure be used in conjunction with a consulting physician rather than an exclusive treatment.

I have (seen, heard) a clear explanation and understand the nature and purpose of the procedure or treatment:

Electrosleep refers to a technique of inducing a relaxed state or sleep by means of transcranial application of a minute amount of current through external electrodes. As supervisor of this project, I (_____) have personally used electrosleep and have found it to be a pleasant, relaxing technique to alleviate somatic complaints.

I have (seen, heard) a clear explanation and understand the benefits to be expected. I understand that the procedure or treatment to be performed is investigational and that I may withdraw my consent for my (his, her) status. With my understanding of this, having received this information and satisfactory answers to the questions I have asked, I voluntarily consent to the procedure or treatment in the paragraph above.

Date

Signed: _____
Witness

Signed: _____
Subject

or

Signed: _____
Witness

Signed: _____
Person Responsible

Relationship

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