

## **Electrosleep: A Double-Blind Clinical Study<sup>1</sup>**

**Saul H. Rosenthal<sup>2</sup>**

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*A double-blind clinical study evaluating the Russian electrosleep technique is presented. Twenty-two patients, mostly outpatients, with neurotic anxiety and depression were each given a course of five half-hour treatments which were either active or simulated electrosleep. In the simulated electrosleep the electrode leads were not connected to the machine. Under these double-blind conditions patients receiving active treatment showed marked clinical improvement that was significantly greater than that showed by patients receiving placebo treatment. Of the 11 patients receiving active treatment 8 made a marked improvement, 2 made a partial improvement, and 1 showed no improvement. Of the 11 receiving inactive treatment, 1 showed marked improvement, 2 showed partial improvement, and 8 showed no improvement. Average "total clinical ratings" on anxiety, sleep disturbance, and depression fell from 11.3 before treatment to 3.2 following treatment. For the patients receiving inactive treatment, average "total clinical ratings" fell from 12.2 to 9.5. Patients receiving active treatment following inactive treatment responded better than patients receiving inactive treatment but did not respond as well as those who received active treatment first. The explanation for this is not clear, but it may reflect a negative expectation following inactive treatment. Patients may have an expectation of failure and a negative placebo effect when the active treatment follows a week of ineffective treatment.*

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<sup>2</sup> Department of Psychiatry, University of Texas Medical School at San Antonio, San Antonio, Texas.

## INTRODUCTION

"Electrosleep" or "cerebral electrotherapy" is a mild, electrical treatment that has been developed by the Russians for the past 24 years. Until approximately 1965 there was little work in this area in Western countries, but within the past six or seven years there has been a vast increase in interest. This has probably been due to a combination of factors including two international conferences on electrosleep and electroanesthesia which were held in Austria, the new availability of translations of the Russian work, and publication of four reviews on electrosleep by the U.S. Library of Congress between 1967 and 1969.

We have published results of clinical studies dealing for the most part with nonblind and single-blind trials of the electrosleep technique (Rosenthal and Wulfsohn, 1970a; 1970b; 1970c). These preliminary results were quite favourable, but due to the possibility that the results may have been due to suggestion, further double-blind studies seemed indicated. The current study presents the results of a double-blind evaluation with 22 psychiatric patients.

## PATIENT SELECTION

The patients included 20 females and 2 males. They ranged in age from 26 to 63, with an average age of 43.1 years. They included two patients in their twenties, nine in their thirties, five in their forties, five in their fifties, and one patient age sixty-three. The patients diagnoses were neurotic and personality disorders with prominent anxiety, depression, and insomnia. Eighteen of the patients had some combination of these symptoms. Of the other four, one patient complained of severe insomnia alone, one of anxiety and severe agoraphobia, one of anxiety and eczema, and one of acute severe anxiety attacks. Two patients were inpatients and 20 patients were outpatients. The patients had been referred specifically for electrosleep treatment or were selected as potentially benefiting from treatment from a psychiatric outpatient clinic. The patients had been receiving a variety of medications without definitive remission. These included minor tranquilizers, tricyclic anti-depressants, sleeping medication, and occasionally phenothiazines. As the patients had for the most part been receiving the medications on a chronic basis, they continued to take their previous medications while they received either active or inactive electrosleep. It was felt that as the medication remained unchanged, clinical changes which were seen could be ascribed to the added treatments.

## DETAILS OF THE DOUBLE-BLIND

After assignment to the double-blind study, patients were evaluated clinically and given self-rating scales by the psychiatrist. They were then

randomly assigned to either active or placebo electrosleep. The psychiatrist who did the rating before and after treatment was not aware of which treatment the patient was receiving.

Of the 11 patients randomly assigned to active treatment, 10 were female and 1 was male. They ranged in age from 26 to 59, with an average age of 42.8. Of the 11 patients assigned to inactive treatment, 10 were female and 1 was male. They ranged in age from 26 to 63, and the average age was 43.5. There were ten outpatients and one inpatient in each group.

The patients were told that they were taking part in a study of electrosleep and that the treatment would be given in two different ways. They were told that if they did not respond to the initial course of treatment, they would receive a subsequent course of treatment with the other type of treatment.

Simulated electrosleep was administered by applying the electrodes in the usual way but not connecting the leads to the machine. When the machine timer is turned on it makes a loud ticking noise and the patients were told that this indicated that the machine was on. Patients receiving active and inactive treatments were not present at the same time so that they were not given an opportunity to compare notes. Although the patients receiving simulated treatment did not feel the tingling sensation which is felt with the active treatment, they did not know that they were expected to feel this.

The only person who knew whether the electrodes were plugged into the machine or not was the operator of the machine. He was not in any way involved with the rating, and he attempted to remain noncommittal with the patients.

#### METHOD OF TREATMENT

The electrosleep machine which we employed was an American-made machine modeled after the Russian Electrosone. It is about the size of a table model radio. It runs on batteries and is not plugged into wall current.

The patients received their treatment wearing whatever clothes they happened to have on at the time. There was no need for any special preparation such as having an empty stomach or removing dental plates as there is no anesthesia or unconsciousness. Two disc-shaped electrodes wrapped in soft cloth and moistened in saline are placed over the orbits and two more behind the mastoid processes. They are held in place by a light mask. The electrodes over the orbits are the cathodes and those behind the mastoid processes are the anodes.

The patients lay down for the treatment in a semidarkened, fairly quiet room. We used a frequency of 100 positive pulses per second and a pulse duration of 1 msec with no base line d-c bias current. The current was regulated so that the patient felt a slight but not uncomfortable tingling sensation over his

or her eyes or mastoid processes. This was usually produced by a current reading of 0.1 to 0.25 mamp on the machine dial. Independent measurement, however, indicated that the true current was 0.5 to 1.2 mamp. Note that the slight tingling is the only thing that the patients feel. They are awake and if the current becomes uncomfortable, we simply turn it down. The individual treatments lasted for one half hour. A course of five treatments was given, and wherever possible it was given Monday through Friday.

The patients may or may not fall asleep during the treatment, whether or not they are receiving active treatment. At the end of the half-hour treatment they are awakened if they have fallen asleep. They feel no confusion, memory loss, or disorientation, although patients receiving an active treatment often reported to the operator that they felt sedated and desired to sleep following the treatment. They usually reported a calm, relaxed sensation during the active treatment.

## MEASUREMENTS OF RESPONSE

The patients were given clinical ratings by the psychiatrist on three areas of symptomatology: anxiety, sleep disturbance, and depression. The ratings were numerical on a seven-point scale in which 0 can be considered as indicating no symptoms, 3 can be considered as moderate symptoms, and 6 would be considered as severe symptomatology. The ratings were given before the first treatment and repeated following the final treatment. The patients were also given the Zung self-rating depression scale before and after treatment. Whenever possible, relatives were questioned for confirmatory evidence and the patient's spontaneous remarks were recorded.

## RESULTS

### Anxiety

The average anxiety rating for patients receiving active treatment fell from 4.3 prior to treatment to 1.4 following treatment. By contrast, patients receiving inactive treatment fell from 4.4 prior to treatment to 3.2 following treatment ( $p < 0.05$  using the  $t$ -test on the D-scores) (Table I).

Following treatment, 4 of the patients receiving active treatment rated zero or asymptomatic, and 5 more had ratings of "1", making a total of 9 out of 11 patients with ratings of "0" or "1". Of the 11 patients receiving inactive electrosleep following treatment no patients were asymptomatic, and only 2 patients had "1" ratings.

**Table I.** Ratings Before and After Active and Simulated Electrosleep Treatment

	Active (N = 11)		Simulated (N = 11)
	Pretreatment ratings	Posttreatment ratings	Pretreatment ratings
			Posttreatment ratings
Anxiety	4.3	1.4	4.4
Sleep disturbance	4.2	0.8	4.2
Depression	2.8	1.0	3.6
Total clinical ratings	11.3	3.2	3.6
Zung self-rating scale	51.3	40.7	51.3

### Sleep Disturbance

The average rating on sleep disturbance for the patients receiving active treatment fell from 4.2 prior to treatment to 0.8 following treatment. By contrast, the patients receiving inactive treatment fell from 4.2 to 3.6 ( $p < 0.01$ ) (Table I). Of the patients receiving active treatment 8 of 11 reported being asymptomatic following treatment. Of the 11 patients receiving inactive treatment only 1 was asymptomatic following the treatment.

### Depression

Average rating on depression for the patients receiving active treatment fell from 2.8 to 1.0. The average rating for patients receiving inactive treatment fell from 3.6 to 2.7 (ns) (Table I). Seven of 11 patients receiving active treatment were completely asymptomatic following the course of treatment. One of the 11 patients receiving inactive treatment was asymptomatic following treatment.

### Ratings on the Zung Scale

One Zung scale was not obtained so data are available for only 10 of 11 patients receiving active treatment. The average rating fell from 51.3 to 40.7. Of the 11 patients receiving inactive treatment, the score remains unchanged, actually rising from 49.6 to 51.3 (ns) (Table I).

### Total Clinical Rating

The "total clinical rating" was defined as the sum of the three clinical ratings on Anxiety, Sleep Disturbance, and Depression. The average total clinical rating fell from 11.3 to 3.2 for patients receiving active treatment, and from 12.2 to 9.5 for patients receiving simulated treatment ( $p < 0.01$ ) (Table I).

### Overall Improvement

Patients were rated as having either marked improvement, partial improvement, or no improvement. "Marked improvement" was defined as a total score of 1 on the total clinical rating. "Partial improvement" was defined as a score between 2 and 9 following treatment and a fall of at least 4 in total score. "No improvement" was defined as any patient who did not fit into either of the above categories.

Of the 11 patients receiving active treatment, 8 showed a marked improvement, 2 showed partial improvement, and 1 showed no improvement. Of the 11 patients receiving inactive treatment, only 1 showed marked improvement, 2 had a partial improvement, and 8 showed no improvement.

### Patients Receiving Active Treatment Following Inactive Treatment

The clinical rater who was ignorant of whether the patient had been receiving active or inactive treatment asked those patients to return for treatments who he felt had not responded to treatment. One of the 11 patients who received active treatment (the patient who made no response) was asked to return for the second course of treatment; the patient did not return. Ten of the 11 patients receiving inactive electrosleep treatments were asked to return for the opposite treatment. Eight of the ten returned. These patients then received a course of active treatment following their course of inactive treatment. The results for these patients were not as satisfactory as for those patients who had received active treatment first. The rating on anxiety fell from 4.0 to 2.5. The rating on sleep disturbance fell from 4.5 to 3.4. The rating on depression fell from 3.4 to 2.0. The total clinical rating fell from 11.9 to 7.9. The average Zung score fell from 54.7 to 50.9 (Table II). Of seven patients who had been previously unchanged, four showed partial improvement and three were still unchanged. One patient had previously shown partial improvement with placebo and that patient showed no further change.

### SUMMARY

A succinct statement of our results is contained in our abstract. The author is aware that the study could not be done under absolutely ideal double-blind

**Table II.** Ratings of Patients Receiving Active Treatment Following Inactive

	Pretreatment	Posttreatment
Anxiety	4.0	2.5
Sleep disturbance	4.5	3.4
Depression	3.4	2.0
Total clinical rating	11.9	7.9
Zung self-rating scale	54.7	50.9

conditions. For instance, there was no way to avoid having the operator of the electrosleep machine know whether or not the patient was receiving active or inactive treatment. We attempted, however, to work within this limitation. Another problem was that the patients receiving active treatment felt a tingling sensation while those receiving placebo treatment did not. We had considered substituting mechanical vibrators, etc., but felt that this was impractical. We decided that the major placebo effect would really be the same for both groups. Both groups were taken from an outpatient situation in which they were seen relatively briefly and infrequently, and were placed in a new treatment setting in which they got a lot of attention, filled out rating forms, were seen daily, were instrumented with electrodes, received a "new treatment" for five half-hour sessions, etc. We felt that the placebo effect coming from this should balance in the two groups and any additional placebo effect from the tingling would be relatively insubstantial and submerged. It is doubted that this could provide enough additional placebo effect to account for the rather striking observed differences.

I cannot help being a little skeptical at our own results. No treatment in common experience is as effective with this type of patient as these results indicate; we suspect that further studies will be less striking in their results. Nonetheless, the results are encouraging and would seem to warrant further investigation and attempts at replication.

## REFERENCES

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