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Department of Psychiatry

University of Minnesota

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Bio-feedback Versus Deep Muscle Relaxation

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TREATMENT OF MIGRAINE HEADACHE:

BIO-FEEDBACK VERSUS DEEP MUSCLE RELAXATION[1]

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There is no general agreement on the definition of migraine. For the purposes of the present study Wolff's definition (Dalessio 1972) was adopted which emphasizes the following features: Migraine headache is periodic, usually unilateral in onset, but may become generalized. The headache is usually associated with irritability, nausea, and sometimes vomiting. Not infrequently the headache is preceded by an aura, particularly of a visual type. Dilatation of the extra-cranial arteries without permanent structural damage is a salient characteristic of migraine.

The pain in migraine headache is believed to be produced by this arterial dilatation together with accumulation of a pain threshold lowering substance in the peri-vascular and subcutaneous tissue of the scalp.

Two treatment groups were included in the present study. Group 1 received operant vaso-motor conditioning or bio-feedback training (vaso-constriction of the extra-cranial temporal artery), and Group 2 received deep muscle relaxation. The specific mechanism of head pain in the migraine syndrome and the feasibility of establishing voluntary control of vaso--motor function according to the operant paradigm, suggested that bio-feedback training to reduce dilation of the extra-cranial arteries might be an effective treatment of the migraine headache. Deep muscle relaxation was employed on the basis of reported personality characteristics of migrainous patients (e.g. Alvarez 1947; Boag 1969; Dalessio 1972; Wolff 1937). Briefly, these patients are characterized by most authors in the field as: anxious,

tense, shy, perfectionistic, achievement oriented, resentful, an easily fatigued individual who reacts to stress, unvented hostility, and resentment with headache. The relaxation group was included in this study to replicate previous studies in this particular respect (Lutker 1972; Mitchell, K. R. and Mitchell, D. M. 1971) and to provide a relevant comparison group.

METHOD

Subjects

Fourteen subjects were used in this study (2 male and 12 female). Their ages ranged from 21 to 54 years, with a mean age of 34. These subjects were divided into two groups. The operant conditioning (bio-feedback) group consisted of 8 subjects, 7 female and 1 male from 21 to 45 years of age with a mean of 32. The relaxation training group was composed of 6 subjects, 5 female and 1 male, with ages ranging from 23 to 56 years with a mean age of 38.

These subjects were obtained from the following sources: Two were members of a large group of students given a battery of psychological tests including a headache questionnaire. Those subjects whose responses suggested a likelihood of migraine were contacted and two of those who did have migraine volunteered to participate in the study. Two other subjects were referred to the experimenter by the University Counseling Service. The remaining ten were obtained through placing an advertisement in the University of Minnesota newspaper, and also through an interview about the study published in the same paper.

Instrumentation

The apparatus consisted of the following components. A piezo-electric pulse transducer, originally designed for use on the finger, was slightly modified for use on the extra-cranial temporal artery. This type of transducer measures changes in pressure and is utilized for monitoring pulse volume. The pulses were fed into a model 350-1500 Sanborn low level preamplifier and from there into a model 150-300 Sanborn Triplexer preamplifier. Pulse wave tracings were obtained from a Sanborn model 151 single channel recorder. A device to detect the pulse amplitude, which made it possible to give differential feedback contingent on pulse amplitude when required, was locally designed and made. Feedback on the subjects' pulse amplitude was possible, when required, by means of a small light which went on and off depending on the level of this variable.

A tape recorder was also used, as well as the following tapes: (a) a Jacobsonian relaxation tape[2], and (b) a relaxation tape using the relaxation instructions from the Stanford Hypnotic Susceptibility Scale[3]. Both tapes are seventeen minutes long.

Procedure

There were three phases in this research: pre-treatment, treatment, and post-treatment. The pre-treatment period lasted for either six or eight weeks. The treatment phase lasted for at least four weeks with two sessions a week. This period was more flexible than the other two depending on the progress of therapy. The post-treatment period, as was the case with the pre-treatment, consisted of six or eight weeks. The events occuring within each of these periods will be described separately under the appropriate heading.

Pre-treatment Phase

In the initial session of this phase a diagnostic interview focussing on headache was conducted. No other information was obtained unless the subject volunteered it. All subjects had been diagnosed by a physician as migrainous and had been suffering from headaches from 7 to 44 years. The experimenter made a point of ascertaining the involvement of the extra--cranial arteries during this interview. If the experimenter agreed with the diagnosis and if the frequency of headaches was high enough for the purposes of this study (since the pre- and post-treatment periods were only of limited duration), the volunteer was included in the study.

In the same session the general nature of the study, the length of its different phases, the two options available (operant conditioning or relaxation), and the rationale for these approaches were explained to each volunteer and each was offered the opportunity to choose the group in which he would be included. This last measure, the choice to be included in either of the two groups, was adopted to minimize the difference on possible placebo effect between the two experimental groups.

Also in this session, if the subject was included in the study, instructions were given for recording the following items of information:

1. Each day the subject was required to record whether he did or did not have a headache.
2. In case of a headache, the subject was to record:
    a. The time the headache began.
    b. The time the headache subsided.
    c. The name and amount of medication taken.

d. The intensity of the headache at its peak, which was rated on a ten point scale where 0 represented absence of pain and 10 represented unbearable pain.

To minimize the errors due to forgetfulness, the subjects were instructed, as mentioned above, to record the absence of headaches as well. Furthermore, subjects were emphatically encouraged to keep records of events as they were happening rather than relying on their memory, and also to keep a record of all headaches whether they believed a certain headache was migraine or otherwise. These measures were taken to minimize the halo effect on the experimental outcome. Later the experimenter excluded the headaches which occurred during an infectious disease or which were otherwise independent of migraine as was clearly decided by a physician. Also the time during which these headaches took place was eliminated from consideration.

In this initial session it was also conveyed to the subjects that they should continue taking their medications as needed, irrespective of therapy. This session is considered to be the beginning of the pre-treatment phase which was either six or eight weeks. The pre- and post-treatment periods were eight weeks each for the first set of nine subjects, and six weeks for a subsequent set of five subjects.

A second session was scheduled one or two weeks after this initial session. The primary purpose of this session was to review the subjects' records and, if necessary, to make corrections, give additional instructions, and answer any questions. Subsequent to this session, the experimenter made occasional phone calls to the subjects, to encourage continued participation, until the beginning of the therapy phase.

Treatment Phase

(a) Operant Conditioning (Bio-feedback) Group. The experiment was conducted in a partially soundproof room in which a comfortable arm-chair was provided for the subject. Upon entering the room he was given at least 5 minutes to rest before the experiment proper began. In the first therapy session the equipment was shown to the subject, the function of its different parts explained, and his questions about the procedure answered.

After a rest period of at least 5 minutes, the transducer was placed on the subject's temporal extra-cranial artery just anterior to the ear on the side of the head in which the subject's headaches occurred, and it was held in place by an earphone-type holder. (If headaches were not confined to one side or could occur on either side, both sides of the head were used in different sessions, practicing more often on the side with more frequent pain.) The subject was instructed to assume a comfortable position and move as little as possible. The pulse from the transducer was amplified to an adequate level and the equipment was set such that pulses above a certain level would turn off the light, located directly in front of the subject, and pulses below that level would turn the same light on immediately. This level was individually set so that some pulses were above and some below it, and hence, the subject received feedback on moment to moment fluctuations of his pulse amplitude. If the pulse amplitude decreased during the session, the feedback threshold was adjusted accordingly. Such an adjustment was always announced. In addition, the experimenter would give verbal feedback on the subject's performance especially when the changes were too large to be adequately reflected by the special light. At these times the subject's behavior was reinforced with expressions such as "fantastic," "marvelous job," "unbelievable," or "doing great."

One very important point is that the feedback available through instrumentation was binary rather than proportional. The prime reason for adding verbal feedback was to provide a proportional quality to it, since it is likely that binary feedback may not be as effective as proportional feedback (although cf. Lang and Twentyman 1974). To avoid providing intermittent reinforcement for poor performance, an effort was made not to adjust the threshold upward, although it was occasionally necessary. The subject was informed that chewing, swallowing, and other slight movements could affect the light and give him false feedback and that he should ignore the changes in the light immediately after such events. Subjects were also informed that they should avoid trying to control the light through changing their breathing pattern, tensing certain muscles, and extraneous activities of this nature.

As soon as a subject seemed to be able to control his extra-cranial temporal artery pulse amplitude with some consistency, efforts were made to reduce his reliance on the light and enable the subject to transfer the learning outside of the laboratory. These efforts were important in that lack of transfer seems to be a major difficulty in a considerable number of therapeutic uses of behavior change techniques. The following two methods were employed to implement this end: (1) methods used during the laboratory training sessions, and (2) methods used outside of the laboratory.

1. A timer was used to provide delayed feedback of up to one minute. However, feedback could be delayed only when the pulse amplitude fell below the established threshold, while as soon as the amplitude exceeded that level the light would go off. In addition the light could be turned off manually, in conjunction with the use of the timer, and the pulse ampli-

tude had to stay below the level for a specified period of time for the light to come on again. (This manual interference was always announced to the subject.) The delayed feedback procedure was designed to reduce the reliance of the subjects on the "external" feedback and increase the reliance on "internal" feedback. To that end the subjects were also encouraged to pay special attention to the differential feeling in the temporal area when the pulse amplitude was high and when it was low. This delayed feedback procedure, when it was used, was in effect only for a portion of the session.

Another measure to reduce the subjects' reliance on the light was to ask them to increase their pulse amplitude, hoping that by changing the pulse amplitude in both directions, subjects would be able to discriminate better the internal cues associated with each of the two conditions. Observation of the pulse tracings throughout the experiment suggests that after trying to increase their pulse amplitude, subjects reduced their pulse amplitude even more, i.e., during the second decrease period the pulse amplitude reached the lowest level during that session.

2. After subjects showed considerable and consistent control over their temporal pulse amplitude, they were asked to practice outside the laboratory at least once a day for at least twenty minutes. For these daily practices outside the laboratory, the subject was instructed to use a comfortable couch or chair with an arm-support. Furthermore, he was directed to place his elbow on the arm-support, lean the palm of his hand gently against the side of his face and situate his index or middle finger on his temporal extra-cranial artery. He was emphatically instructed not to apply any pressure on the artery lest changes in pressure from the finger or hand would produce inaccurate feedback.

At a later stage subjects were asked to take additional steps to incorporate the pulse amplitude practices into their everyday life. They were asked to practice reducing their temporal pulse amplitude without relying on the procedure mentioned above and in progressively more distracting everyday situations in a stepwise fashion. (This was in addition to the daily practice sessions outlined above.) This instruction was designed to enable them to counteract the migraine headache which may strike at any time and which is known to be more manageable in its early stages.

These practice sessions were to be continued, at least for two months following therapy, and then gradually reduced in accordance with frequency of the headache. However, it was recommended that occasional practice should be continued indefinitely.

(b) Relaxation Training Group. This group was treated exactly like the bio-feedback group except for the following:

1. No feedback was given. However, temporal extra-cranial pulse amplitude was recorded precisely as it was for the feedback group for these reasons: (a) to make the sessions more like the ones for the bio-feedback group, thereby reducing the differences in placebo effect between the two groups, and (b) to make it possible to compare the temporal pulse amplitude changes produced by the two procedures.

2. One of the two relaxation tapes was played in each session. The tape was turned on approximately 5 minutes after the temporal pulse amplitude recording began and this recording continued for 5 minutes after the tape ended. This procedure of recording 5 minutes before and after the tapes was adopted for the following reasons: (a) to make the length of the sessions approximately the same for the two groups, and (b) to make

it possible to measure whether any change in the temporal extra-cranial pulse amplitude occurred as a result of relaxation.

To generalize the relaxation outside of the laboratory and incorporate it into everyday situations as much as possible, the following steps were taken: 1. The subjects in the relaxation group were instructed, after the second or third therapy session, to try to relax for no less than twenty minutes at least once a day. They were also encouraged to duplicate at least one of the tapes and use it at home. All six subjects in the relaxation group duplicated at least one of the tapes for use outside of the laboratory. 2. After a subject from the relaxation training group was able to achieve relaxation without much difficulty in the standard position and situation, he was directed to use relaxation progressively more, in a stepwise fashion, during more busy and less relaxed everyday situations.

Post-treatment Phase

This period was the same as the pre-treatment phase in all aspects including the length, with the exception that some booster sessions were scheduled for both groups during the post-treatment period.

RESULTS AND DISCUSSION

Subjects recorded four items of information from which the following five variables are calculated on each subject for each of the three periods, i.e., pre-treatment, treatment, and post-treatment: (1) average number of waking hours of headache per week, (2) average number of headaches per week, (3) average length of each headache, (4) average peak pain intensity, and (5) amount of medication.

Each of these five variables will be treated separately and the changes between the pre- and post-treatment periods will be examined.[4]

(1) Average number of waking hours of headache per week. The mean number of waking hours of headache for the operant conditioning and relaxation groups (19.32 and 17.13, respectively) for the pre-treatment period were not significantly different ($\underline{t} = 0.27$; $p > 0.05$); neither were the variances significantly different ($F = 3.82$; $p > 0.05$).

The change from pre-treatment to post-treatment for the operant conditioning group is highly significant ($\underline{t} = 4.211$; $p < 0.005$), while the change for the relaxation group does not approach significance ($\underline{t} = 0.347$; $p > 0.25$). The changes in these two groups are illustrated in Figure 1. The mean hours of headache for the operant conditioning group decreased from 19.32 to 3.50, a reduction of 82%, whereas for the relaxation group the mean changed from 17.13 to 16.27, a reduction of only 5%.

(2) Number of headaches per week. Here again there were no significant differences between means and variances of the two groups for the pre--treatment period ($\underline{t} = 0.359$; $p > 0.05$ and $F = 3.412$; $p > 0.05$). However, the number of headaches per week changed significantly for the operant conditioning group between pre- and post-treatment ($\underline{t} = 3.503$; $p < 0.005$), but the change for the relaxation group was very slight and non-significant ($\underline{t} = 0.096$; $p > 0.40$). The reduction in the mean number of headaches per week from the pre- to post-treatment period is 66% (from 2.09 to 0.72 headaches per week) for the operant conditioning group and only 2% (from 1.81 to 1.78 headaches per week) for the relaxation group (See Figure 2).

(3) Average length of each headache. There was neither a significant difference between the means of the two groups nor between their variances prior to treatment in regard to average length of each headache ($\underline{t} = 0.665$;

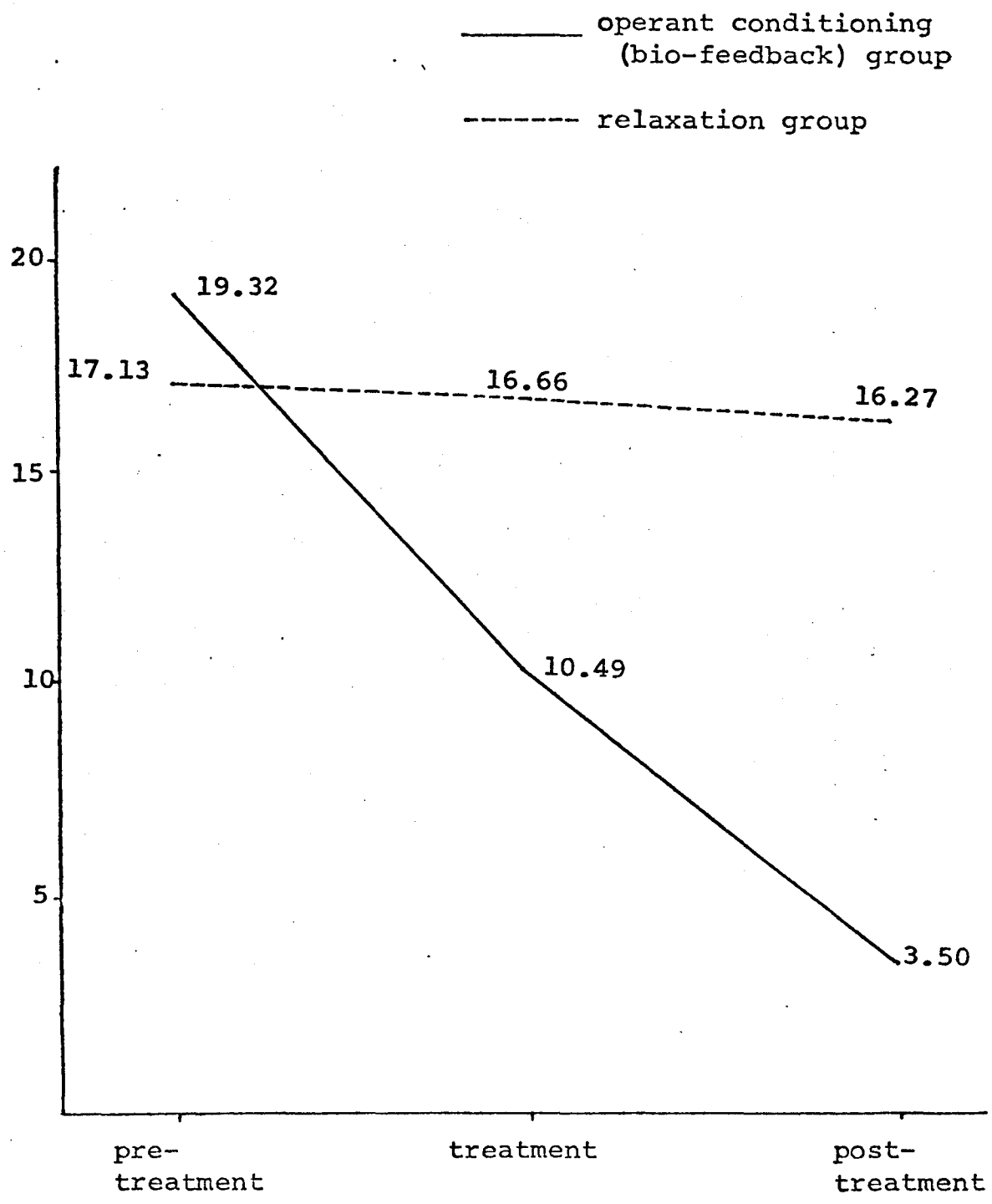

Fig 1 -- Number of waking hours of head-ache per week

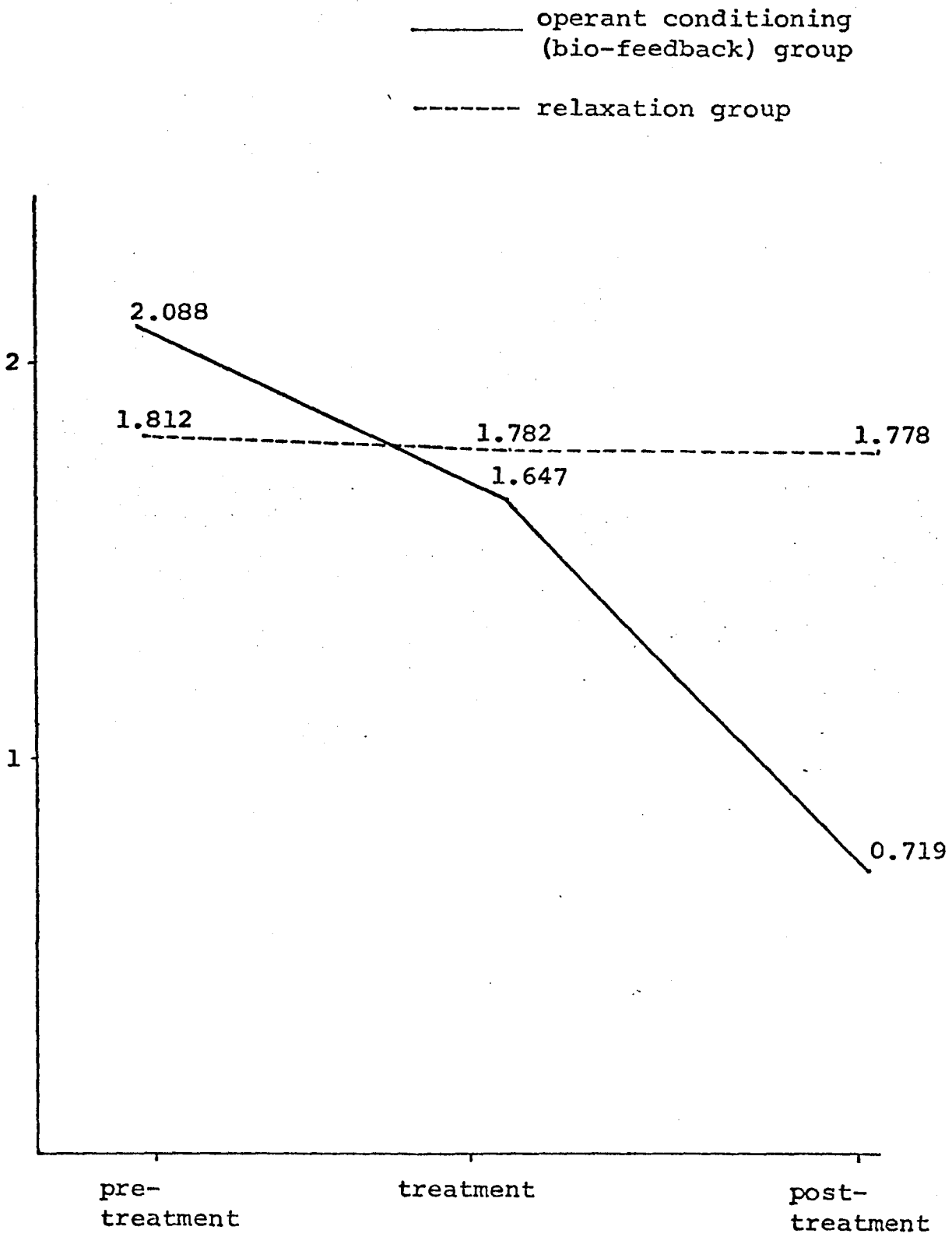

Fig 2 - Number of head-aches per week

$p > 0.5$ and $F = 1.842$; $p > 0.05$).

Decrease in the average length of each headache was significant beyond the 0.005 level for the operant conditioning group ($t = 3.928$), whereas the change for the relaxation group was slight and non-significant ($t = 0.289$; $p > 0.25$). This is reflected in the 37% reduction in the mean length of each headache for the operant conditioning group (from 9.85 to 6.18 hours), as compared to a 3% reduction rate for the relaxation group (from 8.78 to 8.54 hours). This change for the two groups is shown in Figure 3.

(4) Average peak pain intensity. There were no significant differences between the means and variances for the two groups for the pre-treatment period in their average peak pain intensity ($t = 0.805$; $p > 0.1$ and $F = 1.741$; $p > 0.5$). Similarly, neither of the two groups changed significantly at 0.05 level from the pre- to post-treatment period. However, the operant conditioning group approached the 0.05 level of significance ($t = 1.869$, $t_{0.05}$, $df_7 = 1.895$)[5], whereas the relaxation group did not approach this level of significance ($t = 0.599$; $p > 0.25$). The mean reduction for the operant conditioning group was from a 5.05 to 4.23 intensity level, a reduction of 16%, and for the relaxation group this change was from a 4.41 to 4.02 intensity level, a reduction of 9% (see Figure 4).

(5) The amount of medication consumed. Changes in drug intake are shown in Table 1. For comparative purposes, each tablet, capsule, 1 cc injection, and so on, was considered as one unit of medication and a composite score was computed for all medication consumed per week by each subject during each of the three periods. Inspection of Table 1 shows that the subjects in the operant conditioning group who used medication reduced it at least 67% and as much as 100%. The decrease for the group as a whole

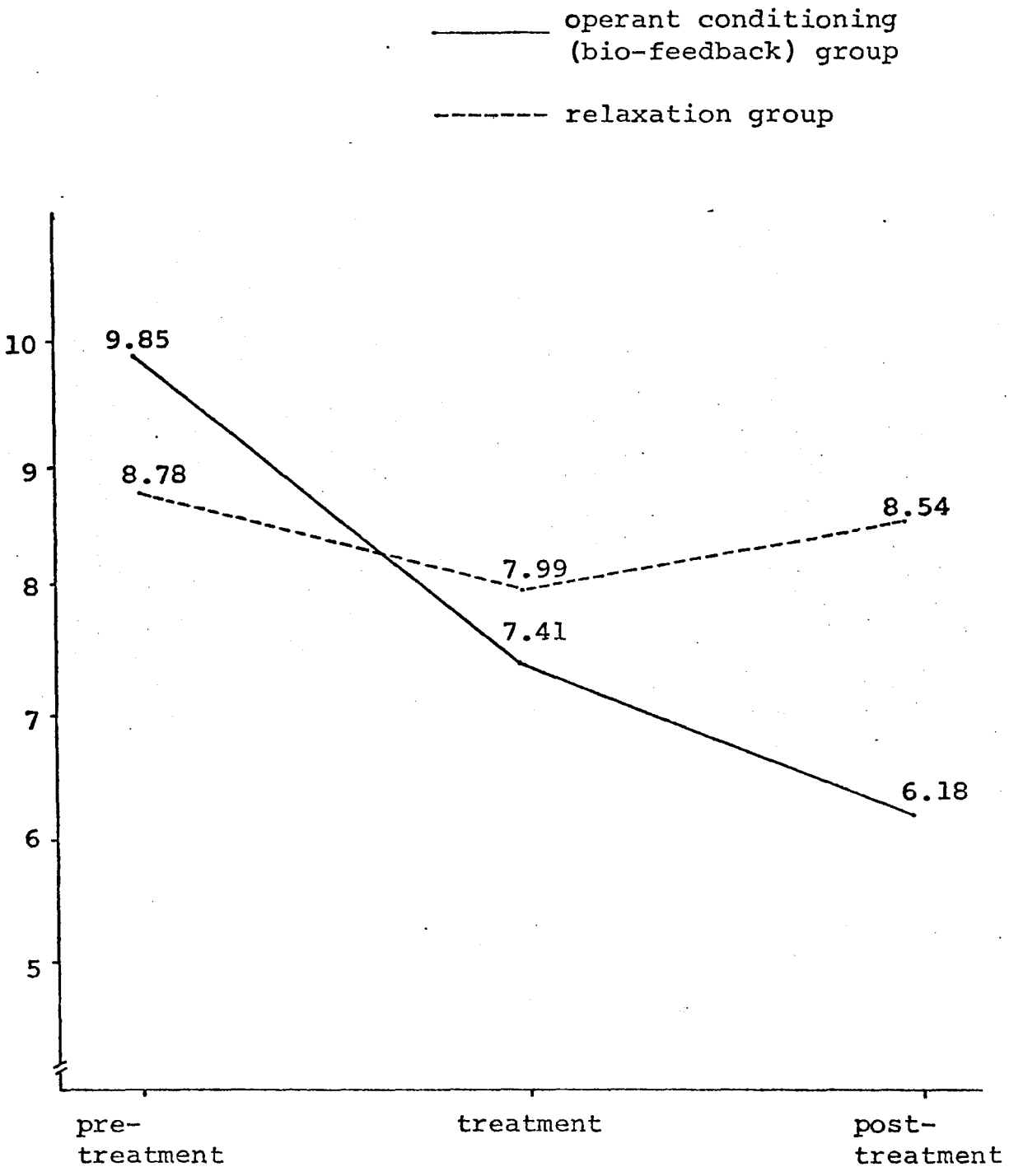

Fig 3 - Average length of each head-ache (only waking hours are included)

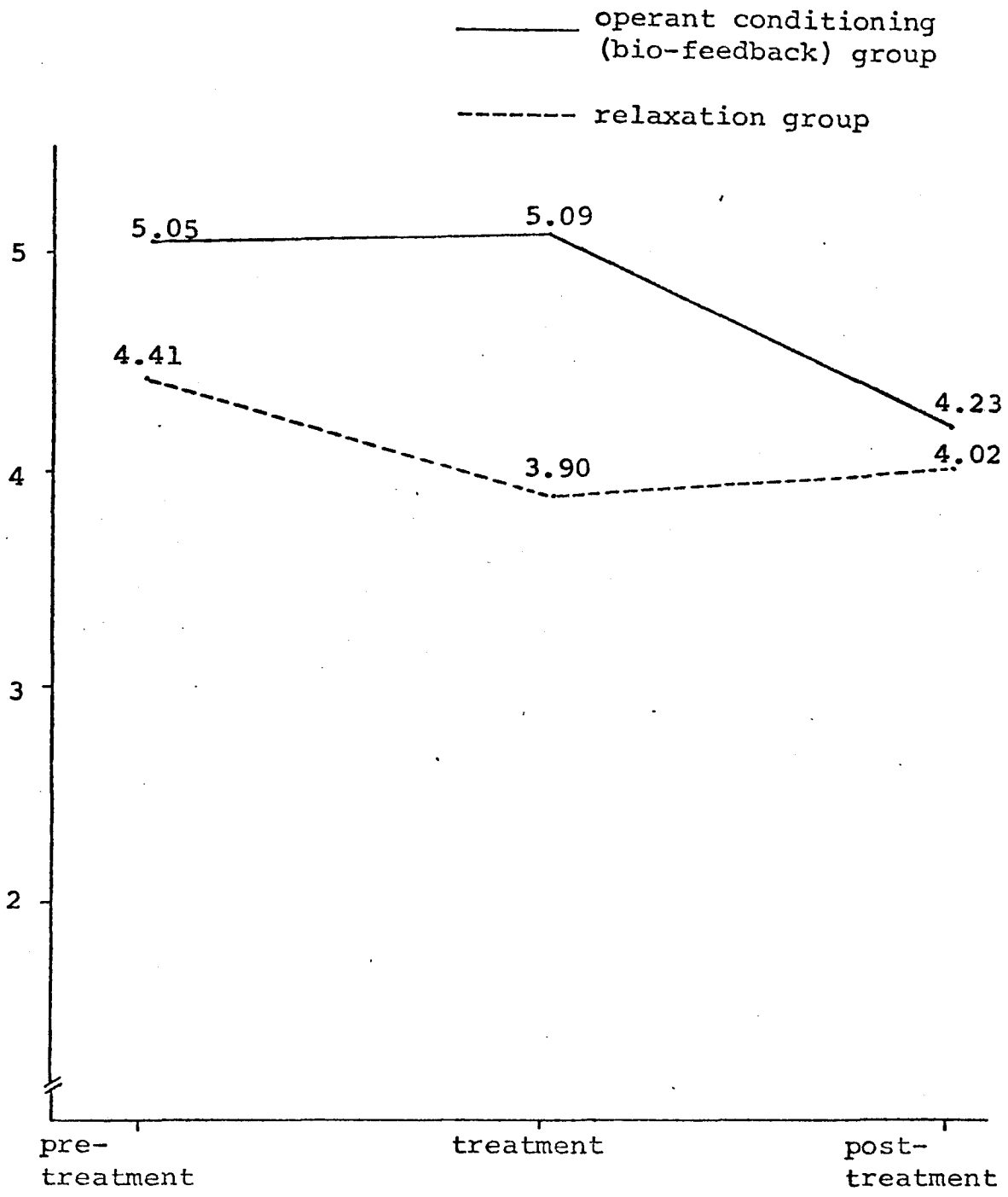

Fig 4 - Average peak pain intensity

was 92%. In contrast, only two subjects in the relaxation group reduced their drug intake after treatment, while the amount increased for the remaining four, with a net increase of 9% in drug consumption for the group as a whole.

No test was used to investigate the statistical significance of changes in the drug intake because different subjects used a variety of types and dosages of medication. Choosing an arbitrary unit, as was done in this text, may suffice for the purpose of rough comparison, but is not adequate for performing statistical analysis.

Observation of the pulse amplitude tracings suggested that this variable was under the control of the subjects in the operant conditioning group. However, due to difficulties involved in obtaining precise measurement of the changes in the pulse amplitude, this type of measurement was not considered justified in the context of this study.

Thus, the operant conditioning (biofeedback) group changed significantly on the first three variables, i.e., number of hours of headache per week, number of headaches per week, and average length of each headache. On the fourth variable, peak pain intensity, the change for this group was not significant. On the fifth variable, amount of medication, there was a considerable reduction from the pre- to post-treatment for the operant conditioning group, but no statistical test was performed.

In contrast, the relaxation group showed no statistically significant decrease in any of the first four variables and no reduction in the fifth variable.

The percentage of change for the operant conditioning and relaxation groups respectively, on each of the five variables, from pre- to post-treatment period, are given in Table 2. The greatest change in the quanti-

Table 1. Drug usage per week (different medications combined).

1a. Operant conditioning group.

Subject	Pre-Treatment	Treatment	Post-Treatment	Improvement	% Improvement
1	0.00	0.12	0.00	0.00	--
2	11.33	4.89	0.00	11.33	100
3	6.00	4.74	2.00	4.00	67
4	15.83	10.98	0.17	15.66	99
5	10.63	5.50	1.75	8.88	84
6	0.25	0.50	0.00	0.25	100
7	26.37	19.35	0.75	25.62	97
8	6.25	6.42	1.63	4.62	74
Total	76.67	52.49	6.29	70.38	92
Mean	9.58	6.56	0.79	8.79	

1b. Relaxation group.

Subject	Pre-Treatment	Treatment	Post-Treatment	Improvement	% Improvement
A	2.67	3.32	6.67	-4.00	-150
B	1.75	0.00	2.00	-0.25	-14
C	4.50	3.42	2.50	2.00	44
D	3.75	2.63	2.75	1.00	27
E	6.50	9.25	6.75	-0.25	-4
F	11.00	16.00	12.33	-1.33	-12
Total	30.17	34.62	33.00	-2.83	-9
Mean	5.03	6.92	5.50	-0.47	

tative aspects of headache (first three variables), occurred in the average number of waking hours of headache per week. This is to be expected, since this measure reflects the composite effect of the number and length of each headache. As such, the number of waking hours of headache can be considered to be a better index of discomfort than other variables employed in this study. A reduction of 82% in this variable for the operant conditioning group is reducing the discomfort due to migraine to a minimal level. This is particularly impressive if we bear in mind that, in the present study, the subjects were instructed to keep a record of all headaches, whether they considered a particular headache to be a migraine or not. Since most people suffer from occasional non-migrainous headahces for one reason or another, an 82% reduction in the total number of hours of all headaches for the group as a whole, could be assumed to reflect an even greater percentage reduction in the number of hours of headache due to migraine alone. Inspection of Table 2 shows that this reduction in discomfort is due more to a decrease in number of headaches (66%), than to a decrease in the length of headaches, although the latter changed to a considerable degree as well (37%).

There was a reduction in medication consumed by the operant conditioning group (92%) along with the decreases in the other variables for this group. This is an impressive finding in that the reductions in experienced headache were accomplished in spite of reducing these subjects' reliance on medication to a minimal level.

The measure of pain intensity in this study does not take into account the general level of pain and its fluctuations throughout a headache, but is only a reflection of peak intensity whether it is momentary or long lasting. As such, this measure is not very revealing. The change in this measure for

Table 2. Percent improvement on the five variables for the operant conditioning and relaxation group.

Variable	Operant Conditioning Group	Relaxation Group
Average number of waking hours of head-ache per week	82%	5%
Average number of head-aches per week	66%	2%
Average length of each head-ache	37%	3%
Average peak pain intensity	16%	9%
Medication consumed	92%	-9%

the operant conditioning group is the least of all five variables (16%), and the only one which is not statistically significant.

Chemotherapy and psychotherapy have been applied to the treatment of migraine headache, generally with unimpressive results with the following exceptions: Methysergide (Curran, Hinterberger and Lance, 1967; Mitchell and Mitchell, 1971; Ostfeld, 1962; Pearce, 1969), combined desensitization (Mitchell and Mitchell, 1971), and thermal biofeedback (Sargent, Green and Walters, 1972; Sargent, Walters and Green, 1973). However, methysergide is only moderately effective and has serious side effects and contraindications, and the precise effect of the thermal biofeedback lacks rigorous experimental demonstration. The comparison of the results of these studies with those of the operant conditioning (biofeedback) technique employed in the present investigation, which is discussed elsewhere (Zamani, 1974), indicates that this operant conditioning procedure appears to be superior to other therapeutic approaches applied to migraine thus far reported in the literature.

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FOOTNOTES

1. This article is based on a thesis submitted by the author to the University of Minnesota in partial fulfillment of the requirements for the Ph.D. degree.

2. It was narrated by Dr. David Wark from the University of Minnesota Counselling Bureau.

3. Narrated by Dr. William Backus from the Hennepin County Medical Health Center.

4. Parametric statistics were used for the first four variables and the results are reported in the text that follows. In addition, non--parametric statistics were applied to the same variables resulting in the same conclusions as derived from parametric statistics, except for the change in the average peak pain intensity for the operant conditioning group, which will be reported in a subsequent footnote. The Wilcoxon matched--pairs signed-ranks test and the randomization test for matched-pairs (Siegel, 1956) are the non-parametric tests employed.

5. However, a non-parametric test, the Wilcoxon matched-pairs signed--ranks test, indicated a significant difference at the 0.05 level.