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Development and Clinical Trial of a Minimal Contact, Cognitive-Behavioral Treatment for Tension Headache[1]

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The effectiveness of two primarily self-administered treatments for chronic tension headache were compared. Twenty-four recurrent tension headache sufferers received either relaxation therapy alone or relaxation training plus cognitive-behavioral therapy in a primarily self-administered treatment format. Both treatments yielded substantial reductions in headache activity and smaller but significant reductions in depression. However, patients who received the combined treatment recorded significantly larger reductions in headache activity than patients receiving relaxation training alone. In addition, high pretreatment levels of headache activity and daily life stress were associated with a poor response to relaxation training but were unrelated to patients' response to the combined treatment. These results suggest that cognitive-behavioral interventions may enhance the effectiveness of primarily self-administered relaxation training, particularly with selected subgroups of patients.

KEY WORDS: headache; cognitive behavior therapy.

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Anita Baker, M.S., was killed in a highway accident on January 3, 1988. We deeply regret the loss of our friend and colleague. Jeffrey Holm, Ph.D., is currently affiliated with the University of North Dakota, Department of Psychology.

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Interest in the use of behavioral treatments for the management of recurrent tension headaches was stimulated more than a decade ago when promising results were reported with biofeedback training (Budzynski, Stoyva, Adler, & Mullaney, 1973). In the ensuing decade more than three dozen studies (excluding case studies) have evaluated the effectiveness of the most commonly used behavioral interventions (EMG biofeedback training and relaxation training, and their combination). Recent metaanalyses indicate that these three treatments produce significant but similar reductions in headache activity in the average patient (Blanchard, Andrasik, Ahles, Teders, & O'Keefe, 1980; Holroyd & Penzien, 1986). Nonetheless, one-third to one-half of tension headache sufferers fail to show clinically significant benefits with these treatments. Therefore, efforts to enhance the effectiveness of commonly used behavioral treatments are still needed.

One promising avenue for increasing the effectiveness of relaxation and biofeedback treatments involves the addition of cognitive behavioral interventions to standard biofeedback or relaxation training procedures (cf., Bakal, 1982; Holroyd, 1986; Holroyd & Andrasik, 1982a; Holroyd, Appel, & Andrasik, 1982). Cognitive behavioral interventions might add to the effectiveness of biofeedback or relaxation training in at least three ways: (a) by enabling patients to alter life difficulties or patterns of thinking that precipitate stress-related headaches (Holroyd, Andrasik, & Westbrook, 1977), (b) by managing the depression that can be both a precipitant and/or a consequence of recurrent tension headache (Holroyd & Andrasik, 1982a), and (c) by addressing the affective and cognitive components of pain, thus enabling patients to more effectively manage pain and distress when headaches do occur (Turk, Meichenbaum, & Genest, 1983). Patients experiencing high levels of daily life stress or depression might therefore be most likely to benefit from the addition of cognitive-behavioral interventions to biofeedback of relaxation training procedures.

Concern about health care costs dictates that methods for reducing treatment costs and increasing the availability of behavioral treatments be developed. One promising method is primarily self-administered treatment. Blanchard and colleagues (Blanchard *et al.*, 1985; Teders *et al.*, 1984) compared the effectiveness of the same relaxation training program when administered in two treatment formats: a 10-session therapist-directed treatment format, or a primarily self-administered treatment format that used manuals and audiotapes to guide patient learning and required only three sessions of therapist contact. The two treatment formats yielded similar (24% and 31%, respectively) reductions in headache activity. This finding deserves replication because it raises the possibility that a minimal contact format can successfully reduce cost and increase the availability of treatment without compromising treatment effectiveness. However, the relatively modest improvements obtained with this treatment suggest that methods of enhancing

the effectiveness of primarily self-administered relaxation therapy require investigation.

The present study compared the effectiveness of two primarily self-administered treatments with chronic tension headaches sufferers: relaxation training alone and relaxation training plus cognitive-behavioral therapy. Patient learning in both treatments was guided by workbooks and audiotaped instructions, with only limited therapist contacts to introduce new treatment elements and to address problems the patients encountered in carrying out treatment. The relaxation training treatment followed the treatment protocol and used the audiotapes and workboooks developed by Blanchard and colleagues (Blanchard *et al.,* 1985; Teders *et al.,* 1984). The cognitive-behavioral treatment was developed for this study and allowed the therapist to tailor treatment goals and treatment techniques to individual client's needs. In addition to measures of headache activity, patient levels of depression and daily life stress were assessed to determine if these variables differentially predicted patient response to the two treatments evaluated in this study.

METHOD

Overview

Recurrent tension headache sufferers participated in the following three phases of the study: (1) a pretreatment evaluation that included a diagnostic assessment, psychological testing, and 2 weeks of daily headache recording; (2) treatment with either relaxation training of cognitive-behavioral therapy delivered in a pimarily self-administered format; and (3) posttreatment and 3-month follow-up evaluations.

Subjects

Tension headache sufferers were selected from individuals who were seeking treatment for headaches at a university research clinic. All patients were self-referred. Fourteen patients were community residents, (7 in each group) and 10 were college students (5 in each group). Patients averaged 15 years education (SD = 2.5) and were 71% female. Mean age was 28 years and ranged from 17 to 41 years (SD = 6.6). Participants had experienced recurrent problem tension headanches for an average of 8 years (SD = 5.7). All patients underwent a medical evaulation by their regular physician in order to be eligible for the study and , where necessary, were evaluated by a board-certified neurologist affiliated with the research clinic.[3] Patients were asked

[3] We greatly appreciate the assistance of Gary Cordingley, M.D., Ph.D.

to sign a data-collection contract, which included a $15 deposit, with the provision that the money would be returned as long as they continued to fill out headache cards and questionnaires, whether or not they stayed in treatment.

Pretreatment Evaluation

Diagnosis. Participants in the study were administered a 1- hour structured interview that assessed general medical history, headache symptoms and history, and psychosocial correlates of headache episodes. Patients were included in the study if they received a primary diagnosis of recurrent tension headaches, if problem tension headaches occurred three or more times per week for at least 1 year, and if they met any two of our three inclusion criteria and none of our exclusion criteria. The diagnostic inclusion criteria were the following: (a) headache described as a continuing dull ache or sensation of tightness, pressure, or constriction; (b) headache described as bilateral and begining in the frontal, occupital, suboccipital, or back-of-the-neck region; and (c) headache described as feeling like a cap or band around the head. The diagnostic exclusion criteria were these: (a) prodromal symptoms commonly associated with vascular headaches, (b) frequent unilateral pulsing or throbbing pain, (c) sudden or abrupt headache onset, and (d) headaches that appeared to be related to a sinus condition. Patients were also excluded if they were already receiving psychological treatment (e.g., psychotherapy, marital therapy) in another setting. Finally, participants who met the above criteria monitored their headache activity for a 2-week period prior to the beginning of treatment to confirm the occurrence of at least three headaches per week.

Psychological Testing. Paticipants were asked to complete the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) and a measure of daily life stress (the Hassles Scale; Delongis, Coyne, Dakof, Folkman, & Lazarus, 1982).

Headache Recording . Participants were asked to record their headache activity on 3 × 5 file cards starting during the 2-week pretreatment assessment. They were asked to chart the severity of their headaches four times daily, at approximately breakfast, lunch, dinner, and bedtime, using an 11-point scale: 0 = no headache; 2 = only aware of headache when attention devoted to it; 4 = headache can be ignored at times; 6 = headache painful, but can continue activities; 8 = very severe headache, difficult to concentrate but can do undemanding tasks; 10 = incapacitating headache. Both verbal and written instruction on how to fill out the cards were given, and compliance was monitored on a weekly basis. Three measures were derived from the recording card information: (a) headache index (the sum of

the four daily headache activity recordings averaged over each week), (b) headache peak (highest headache activity rating each week), and (c) headache-free days per week. Patients were also asked to record prescription analgesics they were taking for headaches. However, only four patients reported regularly taking prescribed medications, so this variable could not be included in any of the subsequent analyses.

Subject Assignment. Participants were matched for pretreatment level of headache activity and randomly assigned to the two treatment conditions with the constraint that the gender composition of the groups be balanced. Twenty-seven patients began treatment, with 14 in the relaxation group and 13 in the combined treatment group. Three patients dropped out of treatment, 1 from the combined group and 2 from the relaxation group, leaving 12 patients per group. There were no significant differences in headache activity, sex composition, age, education, number of years of headache, life stress, or depression between the two treatment groups.

Treatment

Relaxation training and cognitive-behavioral therapy were administered in the same minimal-therapist-contact, home-based format. Patients were seen in three approximately 1-hour treatment sessions, scheduled at the beginning, the middle, and the end of the 8-week treatment. In addition therapists made two 10- to 15-minute phone contacts during the course of treatment to guide skills training. Home training was guided by workbooks and audiocassette training materials during each week of treatment.

Both treatments also included the following elements: (a) didactic explanation of the treatment process (b) self-monitoring of headaches (c) skill training in the clinic (d) homework assigniments with workbooks and audiocassettes and (e) contracting to clarify and facilitate compliance with homework assignments.

Relaxation Training. This treatment followed the protocol and used the programmed instruction materials developed by Blanchard and his colleagues. A detailed description of this treatment protocol can be found in Teders et. al. (1984) and Blanchard and Andrasik (1985). The only change in this relaxation training protocol was based on the suggestion of S. J. Teders (personal communication, September 1983) that relaxation training procedures be somewhat more individualized than was done in his original study. Thus, patients were encouraged to identify the skills they found most useful and to adapt those skills in an individualized fashion in their efforts to manage headaches.

Cognitive-Behavioral Relaxation Therapy. The 1st month of this combined treatment was devoted to relaxation training and the 2nd month to

cognitive-behavioral therapy. In session one, relaxation training was introduced in the same manner as the relaxation-alone treatment. Stress management skills (e.g., problem solving, cognitive restructuring) that would be introduced in the second half of treatment were also explained. Programmed instruction materials covered an abbreviated version of the relaxation treatment in the following 3 weeks. This included relaxation using four muscle groups in week 2, cue control relaxation in week 3, and the application of these skills the daily living in week 4. In addition, patients were asked to monitor circumstances associated with their headaches.

During week 5, patients returned to the clinic for a second treatment session that involved training in more active approaches to stress management. Several steps were taken in the teaching of stress management skills to maximize the possibility that patients would successfully use these skills in spite of the limited therapist contact and support. First, therapist and patient reviewed events frequently associated with the patient's headaches and identified one specific target problem. In selecting this problem, two questions were asked: (a) Is changing this situation (or the patient's approach to managing this situation) likely to have an impact on headache activity? (b) Is behavior change feasible? Stressful circumstances that the patient and the therapist felt optimistic about changing were favored over stressors perceived as unlikely to change.

When a target problem was identified, the therapist determined whether cognitive-restructuring or problem-solving skills appeared more relevant to this problem. Patients who demonstrated haphazard or avoidant problem-solving skills were provided the problem-solving module, while patients who demonstrated well-organized problem-solving strategies but who nonetheless ruminated and worried were provided the cognitive-restructuring module. Programmed instruction materials were tailored for coping with the identified problem. Patients thus learned stress management skills in the context of altering thoughts and behavior associated with a specific stressor. In helping a patient design a specific stress management strategy, therapists asked themselves (and their patients), "What is the smallest possible change that will have a significant impact on the patient's headaches?"

Weeks 6 through 8 were designed to help patients apply the skills learned during the first 5 weeks of treatment. A 10- to 15-minute phone contact during week 6 assisted the patients in working out any difficulties they encountered in using their problem-solving or cognitive-restructuring skills. In week 6, patients also were asked to review the relaxation tapes from the 1st month of training, paying particular attention to the exercises that seemed most helpful. The programmed instruction in week 7 consisted of an overview of the stress management module they had not received in week 5 (e. g., patients

trained in problem solving were asked to look at the cognitive-restructuring module and vice versa). In week 8, patients were asked to review each of the skills introduced in the program, and to assess the skils that were most helpful to them. Patients who were still experiencing problem headaches were instructed on how to apply relaxation and cognitive coping skills to managing headache pain. Finally, at the end of week 8, patients returned to the clinic for an overview of treatment and were encouraged to continue to use the skills they had found most helpful.

Therapists. Therapists were three doctoral students in clinical health psychology, each with at least 3 years' supervised experience administering cognitive-behavioral therapy and relaxation training, as well as experience in the treatment of headaches and other behavioral medicine problems. Training for the present study included role-playing of treatment procedures and ongoing supervision by the senior author throughout the course of treatment. Therapists were also guided by manuals that outlined treatment sessions. the three therapists each treated very close to an equal number of patients in the two treatment conditions.

Ancillary Measures

Homework Compliance. patients were instructed to record the amount of time they spent practicing their homework, including the average amount of time per day and the number of times per day (Steger & Harper, 1980).

Treatment Credibility. Patients completed a measure of nonspecific treatment elements after each of the three treatment sessions and at follow-up. The items included ratings of therapist skill and concern, patient espectations of change, and the importance of making the treatment available to others (Andrasik & Holroyd, 1980). The scale contained nine items that were responded to on an anchored 7-point Likert-type scale (e. g., How effective do you think this treatment will be in reducing your tension headaches? 1 = very effective, 7 = not at all effective).

Posttreatment and Follow-Up Evaluations

At the end of treatment, patients were again asked to complete the battery of questionnaires that had been administered prior to treatment. They were also instructed to continue recording their headaches for 2 weeks. Three months after the completion of treatment, patients were again asked to complete 2 weeks of headaches recording cards.

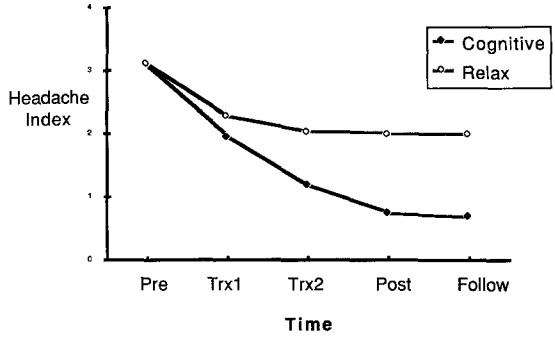

Fig. 1. Daily headache activity at pretreatment, the first half of treatment, the second half of treatment, posttreatment, and follow-up.

RESULTS

Changes in Headache

While both treatments produced substantial reductions in headache activity, patients receiving combined cognitive-behavioral and relaxation therapy showed greater improvements on all three measures of headaches activity than patients receiving relaxation training alone. The changes in headache index for patients in each treatment group are presented in Figure 1. It can be seen that the average patient receiving relaxation training showed a 36% reduction in headache index, while the average patient receiving the combined treatment showed a 76% reduction in headache index. A two-factor (Group × Time) repeated-measures MANOVA was conducted on the three measures of headache activity to test the hypothesis that patients receiving the combined cognitive-behavioral and relaxation therapy would show greater improvement than patients receiving relaxation training alone. A significant effect for Time, $F(9, 156) = 11.11$, $p < .0001$, and a significant Group × Time interaction, $F(9, 156) = 2.26$, $p < .05$, indicated significant reductions in headache activity in both treatment groups but somewhat larger reductions with the combined treatment than with relaxation training alone. Subsequent univariate tests revealed similar results on the three indivdual measures of headache activity: a significant effect for Time and a significant Group × Time interaction on headache index, $F(3, 66) = 39.57$, $p < .0001$ and $F(3, 66) = 4.99$, $p < .01$, respectively; peak headache intensity, $F(3, 66) = 26.86$, $p < .0001$, and $F(3, 66) = 2.75$, $p < .05$, respectively; and headache-free days, $F(3, 66) = 37.18$, $p < .0001$ and $F(3, 66) = 4.14$, $p < .01$, respectively. A priori tests further revealed that patients in the combined treatment showed significantly lower levels of posttreatment scores on

Table I. Headache Activity[a]

	Pretreatment	1st-month treatment	2nd-month treatment	Post-treatment	Follow-up
Headache index					
Combination	3.08	1.95	1.18	0.74	0.68
	(1.31)	(1.09)	(0.93)	(0.94)	(0.95)
Relaxation	3.10	2.27	2.02	1.99	1.99
	(1.75)	(1.99)	(2.26)	(2.27)	(2.09)
Peak intensity					
Combination	6.97	5.77	4.18	2.75	2.91
	(1.13)	(1.76)	(1.71)	(2.11)	(2.42)
Relaxation	7.03	5.33	4.18	4.51	4.60
	(1.54)	(2.33)	(2.90)	(2.59)	(2.89)
Headache-free-days					
Combination	1.27	2.93	4.73	5.71	5.77
	(1.43)	(1.93)	(1.91)	(2.07)	(2.07)
Relaxation	1.57	2.94	3.76	3.82	3.59
	(1.75)	(2.59)	(3.07)	(3.01)	(3.17)

[a]All means are weekly averages over respective 2-week and monthly periods. Means are presented without parentheses and standard deviations are presented within parentheses.

all three measures of headache activity: headache index, $t(1, 22) = 1.83$, $p < .05$; peak headache intensity, $t(1, 22) = 2.06$, $p < .05$; and headache-free days, $t(1, 22) = 2.02$, $p < .05$. Thus, while both treatments produced substantial reductions in headaches activity, patients receiving the combination of cognitive-behavioral therapy and relaxation training were significantly more improved at the end of treatment than patients receiving relaxation training alone.

It can be seen in Table I that treatment gains in both groups were maintained at 3-month follow-up. A two-factor (Group × Time) repeated-measures MANOVA revealed no changes in headache activity in either treatment group from posttreatment to follow-up.

Table II. Daily Life Stress and Depression

	Pretreatment		Posttreatment	
	M	*SD*	*M*	*SD*
Daily hassles				
Combination	108.64	56.80	73.91	36.46
Relaxation	127.56	110.25	136.44	109.40
Depression				
Combination	10.73	7.03	5.36	4.03
Relaxation	10.80	11.75	8.20	9.17

Changes in Depression and Daily Stress

It can be seen in Table II that the combination of cognitive-behavioral and relaxation therapy tended to produce only slightly larger changes in Beck depression scores than relaxation training alone, but that only the combined treatment produced reduction in daily life stress. Two-factor repeated-measures ANOVA revealed only a significant overall treatment effect, $F(1, 19) \times 5.59$, $p < .05$, on Beck depression scores, indicating that the two treatments produced similar reductions in depression. A similar analysis on Hassles scores revealed only a marginal Treatment Group $\times$ Time interaction, $F(1, 18) \times 3.24$, $p < .10$. Analysis of covariance (with pretreatment daily hassles scores as the covariate) suggested that patients receiving the combined treatment reported lower levels of daily life stress at posttreatment than patients receiving relaxation training alone, $F(1, 17) \times 4.72$, $p < .05$.

Predicting Treatment Response

High pretreatment levels of headache activity have been observed to limit the effectiveness of relaxation or biofeedback treatment in at least five studies (Bakal, Demjen, & Kagonov, 1981; Blanchard *et al.*, 1982; Holroyd *et al.*, 1988; Jacob, Turner, Szekely, & Eidelman, 1983; Werder, Sargent, & Coyne, 1981). Also, it has been hypothesized that patients who exhibit high levels of daily life stress or depression will be less likely to benefit from relaxation or biofeedback training than from cognitive-behavioral interventions (Holroyd & Andrasik, 1982a). These hypotheses were supported by our results, which showed substantial simple correlations between pretreatment daily hassles and changes in headache index ($r = -.77$) and pretreatment headache index and changes in headache index ($r = -.76$) for patients in the relaxation group. In contrast, correlations between these variables and improvements in the combined treatment group were nonsignificant. Though it would be premature to draw firm conclusions based on so few subjects, 81% of the observed reduction in headache activity for patients in the relaxation group was explained by pretreatment levels of hassles and headache activity, with both variables contributing significantly to the multiple R ($R = .09$, $F(2, 9) = 18.87$, $p < .05$). Thus higher levels of daily life stress and headache activity were associated with a poor response to relaxation training but were unrelated to patient response to combined treatment.

While initial level of depression was not significantly correlated with change in headache, a cutting score technique (e.g., Jacob *et al.*, 1983) was used to further examine the question of whether depression could predict subsequent change in headache activity. Sixteen patients had initial BDI scores of 8 or greater, 10 in the combined treatment and 6 in the relaxation treat-

ment. In the combined treatment, 8 out of 10 patients had at least a 50% reduction in headache activity. In the relaxation treatment, 3 out of 6 patients achieved a 50% reduction in headache activity. While Fisher's exact test was not significant, given the small cell sizes it is probably premature to rule out the possibility that depression is related to patient response to relaxation training.

Ancillary Measures

There were no differences in compliance with homework assignments in the two treatment conditions. Patients in the relaxation group practiced home training an average of 1.6 times per day, for a total of 22 minutes per day, 4.4 days per week. Patients who received the combined treatment practice home training 2.2 times per day, for a total of 20 minutes per day, 5.7 days per week. A one-factor MANOVA was conducted to determine if there were differences in the duration or frequency of homework in the two treatment groups; there were no multivariate or univariate differences between the two groups, indicating that patients in the two treatments were equally compliant with homework assignments.

It was important to demonstrate that there were no differences in the credibility of the two treatments if the observed differences in treatment effectiveness are to be attributed to treatment characteristics other than credibility. A one-factor MANOVA was conducted on the means (across the three sessions and follow-up) of the nine questions inquiring about treatment elements; there was no multivariate difference between the groups. Because we were seeking to retain the null hypothesis, nine separate t tests were conducted on each question, to help guard against making a Type II error. Of the nine questions examined, there was only one significant difference between the two groups. The relaxation group reported they felt more relaxed during treatment sessions than the cognitive group, $t(1, 20) = 2.14$, $p < .05$. Because the relaxation training group specifically focused on the achievement of a state of relaxation, this difference was assumed to reflect an intended treatment effect rather than a difference in the effectiveness of the treatments in implementing nonspecific elements. The overall results suggest that patients perceived the two treatments as equally credible.

DISCUSSION

A treatment that combined cognitive-behavioral therapy and abbreviated relaxation training was developed for recurrent tension headache sufferers, and the effectiveness of this treatment was compared with a relaxation training program that has proven effective in previous studies. Both treatments were

conducted in a pimarily self-administered treatment format that required only three clinic visits during the 2-month course of treatment. Skills training was guided in large part by audiotapes and workbooks and took place primarily in the patient's home rather than in the clinic. Nonetheless, efforts were made to retain some of the procedural flexibility that characterizes therapist-directed relaxation training and cognitive-behavioral therapy in clinical practice. For example, therapists helped patients identify specific relaxation techniques that they found most useful and emphasized either cognitive-restructuring or problem-solving interventions depending on the apparent source of headache-related stress.

Reductions in headache activity obtained with relaxation training alone compared favorably with results that have been reported not only in previous studies , where relaxation training has been conducted in this primarily self-administered treatment format (Blanchard *et al.* 1985; Tenders *et al.* 1984), but in studies where relaxation training has been administered with greater therapist contact time in a clinic-based treatment format (Blanchard *et al.*, 1980; Holroyd & Penzien, 1986). Thus, this study provides independent support for the Blanchard *et al.* (1985) contention that primarily home-based relaxation training can be a viable alternative to clinic-based training requiring considerably more therapist time.[4]

Cognitive-behavioral intervention appeared to add to the effectiveness of relaxation training in the present study, however, suggesting not only that cognitive-behavioral therapy can be effectively conducted in a primarily self-administered treatment format but that the addition of cognitive-behavioral interventions to relaxation training can significantly enhance the effectiveness of the latter treatment. Significantly larger improvements on all three headache measures were observed with the combination of relaxation training and cognitive-behavioral therapy (e.g., 76% reduction in headache index) than with relaxation training alone (36% reduction[5]). In addition, there was a tendency for patients who received the combined treatment to report larger reductions in daily life stress than did patients who received relaxation training alone.

[4]Converging findings with vascular headache sufferers (see also Jurish *et al.*, 1983; Holroyd *et al.*, in press) similarly suggest that relaxation and thermal biofeedback training can be effectively and economically administered in a primarily self-administered format.

[5]These percentage reflect pretreatment-to-posttreatment difference in group means. When improvement scores for individual subjects are averaged, relaxation training (53% improvement in the average subject) but not the combined treatment (77% improvement) fares better. This is because pretreatment headaches activity scores were negatively correlated with improvement in the relaxation training group but uncorrelated with improvement in the combined treatment group.

To our knowledge, no other studies have compared the effectiveness of relaxation and combined cognitive and relaxation therapies and reported results for at least 10 subjects per treatment group.[6] Two studies (Holroyd *et al.*, 1977; Infantino-Murphy, Lehrer, & Jurish, 1986) comparing the effectiveness of therapist-administered cognitive and relaxation therapies have reported results favoring cognitive therapy, with one of these studies reporting maintenance of treatment differences at 2-year follow-up (Holroyd & Andrasik, 1982b); a third study found no advantage to adding relaxation training to cognitive therapy (Holroyd & Andrasik, 1978). These findings and results from the present study suggest that cognitive therapy is as effective as, and possibly more effective than, relaxation training when evaluations are conducted in general samples of recurrent tension headache sufferers.

However, relaxation training not only is less complicated to administer than cognitive-behavioral therapy but appears to be an effective treatment for many (approximately 50%) recurrent tension headache sufferers. Therefore, cognitive-behavioral therapy might be most economically reserved for patients who are unlikely to respond to relaxation or biofeedback training alone, or who have already failed to respond to one or both of these treatments. In the present study, high levels of daily life stress (assessed by the Hassles Scale) and high levels of headache activity were found to limit the effectiveness of relaxation training (accounting for 81% of the variance of relaxation training outcome), but not the effectiveness of combined relaxation and cognitive-behavioral therapy. Although this finding requires replication, it provides preliminary support for Holroyd and Andrasik's (1982a) hypothesis that cognitive behavior therapy is more effective than relaxation or biofeedback treatments for patients experiencing high levels of daily life stress. It also raises the possibility that patients with high levels of headache activity may be more responsive to cognitive-behavioral therapy than to relaxation training. Future studies evaluating the effectiveness of cognitive-behavioral interventions might, therefore, profitably focus on subgroups of patients hypothesized to be unresponsive to relaxation or biofeedback training, rather than on heterogeneous samples of recurrent tension headache sufferers that are likely to contain a significant proportion of patients who can benefit from simpler relaxation training interventions.

[6]Mean improvement scores calculated with fewer than 10 subjects are unreliable because a single outlying observation may dramatically distort the mean. There is also no method for detecting such outliers in such a small sample (Kraemer, 1981). In addition, when comparing two effective treatments using small samples, reliable differences in treatment effectiveness are likely to be undetectable. For example, power analysis indicates that to have an 80% chance of detecting a 15% difference in the effectiveness of two treatments (e.g., 65% vs. 50% reduction in headache activity) requires between 25 and 30 subjects per treatment group.

Attempts were made to equate the two treatments evaluated in this study on nonspecific treatment variables (e.g., amount of clinic time, duration of treatment, amount of time in skills training). Patients rated the two treatments as equally credible, important, and effective in helping them control their headaches. Participants also rated therapists as equally skilled and concerned and themselves as having similar expectancies for improvement. In addition, patients in the two treatment groups recorded similar amounts of time spent in therapy-related activities at home. These findings make it more plausible that differences in treatment outcome were due to differences in the content of treatment procedures that were the focus of this study rather than to other treatment variables, though the latter possibility cannot be completely ruled out.

In summary, our results provide independent support for the use of primarily home-based relaxation training in the treatment of recurrent tension headache and initial evidence that cognitive-behavioral therapy can increase the effectiveness of relaxation training for at least some patients. Preliminary support was also found for the hypothesis that high levels of daily life stress limit the effectiveness of relaxation training but not the effectiveness of combined cognitive-behavioral therapy and relaxation training. These treatment results are from a relatively small sample of patients and therefore require replication before they can be accepted with confidence. Nonetheless, they suggest that cognitive-behavioral interventions may be effective with some patients who are unresponsive to simpler interventions such as relaxation training.

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