

Cognitive-behavioral Therapy Versus Temporal Pulse Amplitude Biofeedback Training for Recurrent Headache

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Sixty-four headache sufferers were allocated randomly to cognitive-behavioral therapy (CBT), temporal pulse amplitude (TPA) biofeedback training, or waiting-list control. Fifty-one participants (14M/37F) completed the study, 30 with migraine and 21 with tension-type headache. Treatment consisted of 8, 1-hour sessions. CBT was highly effective, with an average reduction in headaches from pre- to posttreatment of 68%, compared with 56% for biofeedback, and 20% for the control condition. Headaches continued to decrease to 12 month follow-up for CBT. Improvement with CBT was associated with baseline coping skills, social support, and physiological measures at rest and in response to stress, particularly TPA. Changes on some of these measures were correlated with changes in headaches. No significant predictors of response to biofeedback emerged.

BEGINNING IN THE EARLY 1970s, a number of psychological treatments have been developed for recurrent or primary headaches (i.e., migraine and tension-type headache) (Rains, Penzien, McCrory, & Gray, 2005). These treatments can be broadly categorized into physiologically oriented techniques and cognitive behaviorally oriented methods. The

former category encompasses the various types of biofeedback training such as EMG biofeedback, thermal biofeedback, pulse amplitude biofeedback, EEG biofeedback, and skin conductance biofeedback. The latter category includes the various forms of relaxation training such as progressive relaxation and autogenic training, hypnosis, transcendental meditation, and cognitive-behavioral therapy (CBT). The literature on some treatments is much more extensive than on others, but when comparisons between treatments have been made, studies have usually failed to find significant differences. Early examples include P. Martin and Mathews (1978) finding no significant difference between EMG biofeedback and relaxation training for tension-type headache and Blanchard, Theobald, Williamson, Silver, and Brown (1978) finding no significant difference between thermal biofeedback training and relaxation training for migraine. Reviews have supported the findings of these comparative studies by reporting no differences across all the more extensively evaluated treatments (e.g., Blanchard, Andrasik, Ahles, Teders, & O'Keefe, 1980; Holroyd & Penzien, 1986; Primavera & Kaiser, 1992).

Research has shown that psychological treatments consistently lead to a significant reduction in headaches and improvement on other variables (e.g., reduced medication intake, decreased psychosomatic symptoms, improved mood). Well-controlled studies have demonstrated that the effects are more than a placebo response (e.g., Blanchard et al., 1990; Holroyd, Andrasik, & Noble, 1980), and meta-analytic reviews have quantified the differences. Rains et al. (2005) summarized the results of five meta-analytic reviews for psychological treatment of migraine (thermal biofeedback, EMG biofeedback, CBT,

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and relaxation training) published between 1980 and 1999, and concluded that average improvement ranged from 35% to 55%, compared with 5% for no-treatment controls. These authors also summarized the results of four meta-analytic reviews for psychological treatment of tension-type headache (EMG biofeedback, CBT, and relaxation training) published between 1980 and 2001 and concluded that average improvements again ranged between 35% and 55%, compared with 2% for no-treatment controls.

Although research has established the utility of psychological treatment for headaches, currently available treatments fall well short of the goal of being able to help all chronic headache sufferers reduce the frequency, intensity, and duration of their headaches to acceptably low levels. This raises the question: How can more effective treatments be developed? Although the research literature generally suggests the equality of different treatments, two treatments look more promising than alternatives, one from the cognitive-behavioral domain and one from the physiological domain. CBT derives its name from the utilization of techniques that specifically target both cognitive and behavioral change. CBT involves a number of different techniques including self-monitoring, education, relaxation training, and pain-management strategies, in addition to techniques directed at maladaptive thoughts and underlying beliefs. CBT has been shown to be superior to the well-established treatment of EMG biofeedback training for tension-type headache sufferers (Holroyd, Andrasik, & Westbrook, 1977). Other studies have reported positive results using this approach with migraineurs (Knapp & Florin, 1981; Sorbi & Tellegen, 1986). These results from controlled trials have been supported by findings from a large, single group outcome study (Bakal, Demjen, & Kaganov, 1981) and two series of single-case experiments (Anderson, Lawrence, & Olson, 1981; Kremsdorf, Kochanowicz, & Costell, 1981).

The physiological treatment that stands out is biofeedback training in which feedback is provided with respect to pulse amplitude recorded from the superficial temporal artery, usually from the side on which pain is experienced most frequently. Elmore and Tursky (1981) demonstrated that this approach was significantly more effective than the well-established treatment of thermal biofeedback training, and Bild and Adams (1980) showed this form of training was superior to EMG biofeedback training. Not all studies have found this type of biofeedback training to be superior to alternative treatments, however (e.g., Gauthier, Lacroix, Coté, Doyon, & Drolet, 1985).

The study reported here compared these two promising approaches, CBT and temporal pulse amplitude (TPA) biofeedback training, using versions designed to increase effectiveness. The CBT approach employed in the study was based on a functional model of headaches that conceptualizes headaches as occurring as a function of antecedent factors and consequent events (Martin, 1993). This variation of CBT is broader than the earlier versions developed by the pioneers in the field, as the earlier versions tended to equate headaches with stress, whether the emphasis was on stress as a precipitator of headaches (cf. Holroyd & Andrasik, 1982) or headaches as stressors (cf. Bakal et al., 1981). This variation incorporated stress as a precipitant and headaches as stressors, but also took into account other controlling variables of headaches such as alternative trigger factors (e.g., noise, glare, and eating certain foods), and reinforcement mechanisms.

TPA biofeedback training as used in this study had the advantage that previous studies have demonstrated that the variable used for feedback training was associated with peripheral headache mechanisms (e.g., Martin, Marie, & Nathan, 1992; Martin & Seneviratne, 1997; Martin & Teoh, 1999). Also, the feedback was more sophisticated than in most previous studies as information was provided on each heartbeat, showing how pulse amplitude varied compared with the last block of 10 trials, and periodic displays showed progress across the session.

Little is known about the mechanisms of psychological treatment for headaches. Newton and Barbaree (1987) assessed cognitive changes associated with CBT and found that, in comparison with untreated controls, treated subjects appraised headaches in a more positive manner and reported more frequent occurrence of coping thoughts of a problem-solving nature. Changes in cognitive appraisal were correlated with reduction in headache intensity. Studies of biofeedback training have generally failed to support the physiological rationale of the treatment programs. Training patients to increase EMG is as effective for reducing headaches as training them to decrease EMG (Andrasik & Holroyd, 1980), for example, and training them in "hand cooling" is as effective as training them in "hand warming" (Gauthier, Bois, Allaire, & Drolet, 1981). Holroyd et al. (1984) responded to these findings by proposing an alternative model of therapeutic change that assigns a central role to cognitive mediators. These authors have suggested that patients' perceptions of success with biofeedback leads to them viewing their headaches as having a more internal locus of control and themselves as more self-efficacious. These cognitive

changes lead to new efforts to cope with headache-related stresses that, in turn, alter stress-responses triggering headaches. This model has undergone small revisions over the years but is still promoted currently (e.g., Holroyd, Martin, & Nash, 2006). Both Holroyd et al. (1984) and Mizener, Thomas, and Billings (1988) have presented data consistent with this model of change with biofeedback training. In the former study, for example, changes in self-efficacy and locus of control during EMG biofeedback training correlated with reduction in headache activity, whereas changes in EMG activity were uncorrelated with outcome.

Studies of the mechanism of TPA biofeedback training have produced inconsistent results. Gauthier and colleagues found no significant relationship between learning to control TPA and headache reduction (Gauthier, Doyon, Lacroix, & Drolet, 1983; Gauthier et al., 1985) but Lisspers and Öst (1990) reported a significant relationship. Falkenstein and Hoormann (1987) noted changes in other physiological variables monitored, such as blood pressure, heart rate and skin temperature, in parallel with TPA changes, and suggested that learned sympathetic activation may account for reduction in TPA with this type of biofeedback training. This study will investigate the treatment mechanisms question by exploring three sets of variables: (a) changes in the cognitive-behavioral skills (cognitive appraisal and coping skills) that are the main focus of CBT; (b) changes in the physiological variables (TPA and other measures of sympathetic activation) that are the target of TPA biofeedback training; and (c) changes in the cognitive mediators (self-efficacy and locus of control) that have been suggested as underlying biofeedback training and that may underlie CBT.

Another limitation of the current literature is that little is known about predictive factors and the related important issue of client-treatment matching. Headache classification systems seek to partition headaches according to underlying mechanisms on the assumption that achieving this goal will have implications for headache management. With respect to psychological treatment of recurrent headache, however, there is little evidence to support differential efficacy as a function of diagnosis: tension-type headache and migraine seem to respond equally to the various psychological treatments, including EMG biofeedback training (Bakal & Kaganov, 1977), CBT (Bakal et al., 1981), self-management training and cognitive therapy (Martin, Nathan, Milech, & van Keppel, 1989), and relaxation training (Williamson et al., 1984). Most of the psychological literature on treatment of headaches, however, was published

during the 1970s and 1980s using a classification system published some years earlier (*Ad Hoc Committee, 1962*). A new classification system with operational diagnostic criteria was published in 1988 (*Headache classification committee of the International Headache Society, 1988*) and a revised edition in 2004 (*Headache classification subcommittee of the International Headache Society, 2004*), which may have greater prognostic value.

Some studies in the headache literature have produced weak findings relevant to client-treatment matching (Martin et al., 1989; Sorbi, Tellegen, & Du Long, 1989; Tobin, Holroyd, Baker, Reynolds, & Holm, 1988), but these studies have investigated a range of variables that have limited theoretical justification. An approach to client-treatment matching that seems more defensible is the one adopted in the anxiety field, in which researchers have utilized Lang's three-systems theory for this purpose, a theory that conceptualizes anxiety as comprising three components: cognitive, behavioral, and physiological (Lang, 1971). In a series of studies, Öst and colleagues allocated anxious patients to either a physiological or behavioral treatment based on whether they showed fear predominantly on a physiological or behavioral measure (Öst, Jerremalm, & Jansson, 1984; Öst, Jerremalm, & Johansson, 1981, 1982). They demonstrated, in samples of social phobics, claustrophobics, and agoraphobics, that those given treatment consonant with the expression of their fears, fared best. Michelson (1986) extended this approach by adding patients with predominantly cognitive fears and showed that agoraphobics given a treatment directed at the main aspect of their fear improved most, particularly at follow-up. Haug et al. (1987) presented data supporting the consonant treatment concept with patients suffering from fear of flying. This study investigated the client-treatment matching issue by evaluating whether individuals who have the most abnormal scores before treatment on TPA and other measures of sympathetic activation benefit most from the physiological treatment (biofeedback training), whereas individuals who have the most abnormal scores before treatment on the cognitive-behavioral variables of appraisal and coping benefit most from CBT.

Method

PARTICIPANTS

Participants were recruited by advertising in the local community for headache sufferers to volunteer for a study on psychological treatment. Par-

ticipants were required to meet the following criteria: (a) headaches satisfying the criteria for “migraine with typical aura,” “migraine without aura,” or “tension-type headache” (including all subtypes) (Headache classification committee of the International Headache Society, 1988); (b) headache chronicity of 12 months or more; (c) headaches of sufficient frequency, intensity, and duration that they achieve an average score of at least 0.30 on the main dependent variable (composite index calculated from hourly headache ratings recorded on cards) during the first 2 weeks of record keeping; and (d) age between 19 and 65 years.

Sixty-four individuals volunteered, met all the selection criteria, participated in the initial three assessment sessions, and were allocated randomly to the three treatment conditions. Fifty-one participants completed the treatment program including the posttreatment assessment, resulting in a dropout rate across the three conditions of 20.3%. Demographic characteristics of the participants who completed the treatment program are presented in Table 1. The proportion of migraineurs was 58.8% and of females was 72.5%. The average headache chronicity was very high (24.7 years). The three groups were compared on the four variables in Table 1 using ANOVA (age, chronicity) or χ^2 (gender, diagnosis). Differences fell well short of significance on all four variables.

The dropouts occurred as follows: (a) CBT, 4; (b) biofeedback, 3; and (c) waiting-list control, 6. Although the dropout rate was highest in the control group, χ^2 indicated that the dropout rate did not significantly differ across the three groups. The 13 participants who dropped out were compared with the 51 participants who completed treatment on the four variables in Table 1 using ANOVA or χ^2 . None of the differences approached significance. Participants did not receive any reimbursement for taking part in the study.

MEASURES

Psychological Assessment of Headache Questionnaire (PAHQ; Martin, 1993). The PAHQ

is an interviewer-administered questionnaire that collects information on personal and social history; headaches and associated symptoms; functional analysis; and assessment and treatment history. The PAHQ was administered for three reasons. First, it elicits information that is necessary for planning CBT. Second, it provides information for describing the participant sample. Third, it provides information for diagnosing headaches according to the operational criteria of the IHS.

Daily Cards (Martin, 1993). Records of headaches and medication usage were kept on daily cards. On one side of the card, participants record name, date, and any medication taken (name of drug, dosage, time of ingestion). On the other side, they monitor their headaches by rating headache intensity hourly on a 6-point scale throughout the waking day and placing crosses on graphs at the point of intersection between the rating and the hour of the day. Such cards have been recommended as the principal dependent measure for assessing outcome in the recently published “Guidelines for Trials of Behavioral Treatments for Recurrent Headaches” (Penzien et al., 2005).

Cognitive-behavioral skills. Cognitive-behavioral skills were assessed via the Cognitive Appraisal Inventory (CAI; Holm, Holroyd, Hursey, & Penzien, 1986) and Coping Strategies Inventory (CSI; Holm et al., 1986; Tobin, Holroyd, Reynolds, & Wigal, 1989). These questionnaires differentiate between headache sufferers and matched headache-free controls (Holm et al., 1986; Ehde & Holm, 1992). The CAI consists of 10 items designed to assess a participant’s appraisal of potentially stressful events and includes three subscales: Perceived Impact, Perceived Control, and Perceived Predictability. The CSI consists of 72 items designed to assess coping strategies used in responding to stressful life events and includes eight subscales. Four subscales measure “engagement” strategies: problem solving, cognitive restructuring, social support, and express emotion. The other four subscales measure “disengagement” strategies: problem avoidance, wishful thinking, social withdrawal, and self-criticism.

Table 1
Demographic characteristics of participants

| Variable | Treatment conditions | | | Total (n=51) |
|-------------------------------|----------------------|--------------------|----------------|-----------------|
| | CBT (n=20) | Biofeedback (n=19) | Control (n=12) | |
| Gender | 6M/14F | 6M/13F | 2M/10F | 14M/37F |
| Mean age in years (SD) | 39.9 (11.3) | 46.0 (8.0) | 47.7 (6.4) | 44.0 (9.6) |
| Diagnosis | 14MG/6TT | 9MG/10TT | 7MG/5TT | 30MG/21TT |
| Mean chronicity in years (SD) | 24.4 (12.1) | 22.6 (11.6) | 28.4 (11.2) | 24.7 (11.7) |

Note. M=male; F=female; SD=standard deviation; MG=migraine; TT=tension-type headaches.

Physiological variables. Temporal pulse amplitude (TPA), blood pressure (BP), heart rate (HR), and forehead electromyographic (EMG) activity, were measured under conditions of rest, stress and post-stress recovery as in our previous studies (Martin & Seneviratne, 1997; Martin & Teoh, 1999). Assessment was carried out in a sound-attenuated, temperature-controlled (20 °C–22 °C) psychophysiology laboratory. The main items of equipment were a Grass Model 7D polygraph and upgraded Macintosh LC475 8/160 computer. A National Instruments Model LC DAQ internal multifunction data acquisition card was used for sampling analogue voltages and controlling external hardware. Analysis of the physiological signals recorded by the polygraph was carried out using LabView (1994) software. Control of monitors was achieved with HyperCard 2.2 (1993).

TPA is thought to be a measure of arterial distention caused by the passage of the pressure pulse. TPA was recorded from a photoelectric pulse sensor (model PPS) placed over the zygomatic-facial branch of the superficial temporal artery on the side of the head from which each participant most commonly experienced headaches. The 1/2 amplitude high frequency control was set at 500 Hz, and the input selector switch to TC.8. The LabView application detected minimum and maximum values, and TPA was the difference between successive minimum and maximum values. BP was assessed by recording the R-wave to pulse interval (RPI). RPI is the interval between the occurrence of the ECG R-wave and the arrival of the associated pressure pulse at a point in the temporal artery. RPI is inversely correlated with systolic BP and to a lesser extent with diastolic BP (Marie, Lo, Van Jones, & Johnston, 1984). The LabView application calculated RPI from the ECG signal, which revealed the occurrence of the R-wave, and the signal from the pulse sensor, which indicated when the pulse arrived at the temporal recording site. Interbeat interval (IBI) is the interval in milliseconds between successive ECG R waves and is, therefore, an inverse correlate of HR. The ECG was recorded from three electrodes attached to the top of the sternum, fifth left intercostal space, and left elbow. EMG was recorded from three electrodes attached to the forehead 2.5 cm above the eyebrows, with the live electrodes placed above the eyes and the ground placed in the center of the forehead.

Cognitive mediators. Self-efficacy and locus of control were assessed using updated versions of the measures developed by Holroyd et al. (1984) in their study of the mechanisms of biofeedback training. The Headache Self-Efficacy Scale (HSES)

calls for participants to rate their confidence in their ability to prevent the occurrence of headaches in 51 situations frequently associated with the onset of headaches in vulnerable individuals (Martin, Holroyd, & Rokicki, 1993) and yields a single measure. The Headache-Specific Locus of Control Scale (HSLC) consists of 33 items for which participants indicate the degree to which they believe that the variables controlling headache activity are primarily internal or external (Martin, Holroyd, & Penzien, 1990). The HSLC has three subscales: healthcare, internal, and chance.

TREATMENT CONDITIONS

CBT. This approach proceeded as described in P. Martin (1993). All participants received education, relaxation training (progressive relaxation or autogenic training), pain management training (imagery training and attention-diversion training), and cognitive training to modify dysfunctional thoughts and underlying beliefs. If functional analysis indicated that other techniques were appropriate, and time permitted, other techniques were used to modify the controlling variables of the headaches, that is, the immediate, setting, onset and predisposing antecedents, and immediate and long-term responses of the headache sufferers and significant others. The therapists maintained records of the amount of time they used each approach with the following results: education, 18%; progressive relaxation training, 34%; autogenic training, 13%; imagery training, 7%; attention-diversion training, 3%; cognitive training, 23%; and "other," 6%. Homework assignments were set in each treatment session, and participants maintained records of all the practice that they completed on one of six types of diaries, designed for ease of recording of the different techniques used. All the diaries required participants to record practice start and finish times, and ratings that indicated perception of success (e.g., relaxation ratings before and after relaxation practice).

Pulse amplitude biofeedback training. Feedback of TPA was provided from the superficial temporal pulse artery on the side of the head that headaches were most frequently experienced. The display that appeared on the monitor during 15-s trials consisted of a vertical red pipe that was adjusted in diameter every heart beat to represent TPA. A red pipe was used to assist imagery in home practice as it was reminiscent of an artery. Three vertical lines were drawn on each side of the display. The distance between the middle lines in each grouping represented average TPA on the previous trial, and the lines to either side of the middle lines represented 10% greater or lesser than this value. Hence,

participants received beat-to-beat feedback and could see how current TPA compared with average TPA on the last trial.

Each trial was followed by an intertrial interval of 5-s during which a display appeared showing average TPA on the trial just concluded and average TPA on the trial before. If TPA in the trial just ended was lower than in the previous trial, the word *good* appeared. At the end of each block of 10 trials, a histogram was displayed that showed average TPA for each block of 10 trials completed. Hence, participants also received feedback on progress across the session. Each treatment session consisted of 2 blocks of baseline trials in which no feedback was provided, followed by 10 blocks of training trials. This condition was associated with instructions to practice at home, in parallel with the CBT condition. Participants completed diaries of practice start and finish times, and success ratings.

Waiting-list control. Participants in this condition received no treatment for a period of time equivalent to the period over which treatment was administered to participants in the other two conditions. They completed the same assessment instruments, including self-monitoring, as participants in the other two conditions. Participants in this condition were offered treatment after completing the "posttreatment" assessment, as it was considered unethical to withhold treatment any longer.

THERAPIST TRAINING AND SUPERVISION

Therapy was administered by one of four psychologists. Two had completed professional training, accomplished in Australia via a 4-year undergraduate degree and 2-year master's degree, and both had several years of posttraining experience. The other two were enrolled in a Ph.D. program. Two of the therapists were female. Prior to the commencement of the study, the therapists were trained in the treatment techniques by the first author, a clinical psychologist with 27 years of experience treating headache sufferers, and author of the CBT manual (Martin, 1993). The author used the same training format as he has used in 7-hour workshops conducted for purposes of continuing education. The author met with the therapists each week throughout the treatment period to provide clinical supervision.

PROCEDURE

Individuals responding to the advertisements underwent a preliminary screening by phone. Those satisfying the selection criteria attended three assessment sessions scheduled weekly prior to commencing treatment. In the first session,

participants completed a consent form, started the PAHQ, and completed the Life Events Inventory (LEI), a scale that has to be administered prior to completion of the CAI. Participants were then given training in self-monitoring headaches and medication consumption using the daily cards. This training was supplemented by providing take-home materials (written instructions and completed exemplar cards). Participants were asked to start the self-monitoring on the day after the first session, and were given copies of the CAI and CSI to complete at home.

With respect to medication, participants were told that whether they consumed medication was their choice. They were also told that it would suit the research study if they did not start any new medication during the study. It was suggested to them that as treatment progressed and they experienced fewer headaches, they may decide to take less medication.

Headache diagnosis was accomplished by a two-step checking procedure (Martin & Teoh, 1999). First, the PAHQ includes 16 diagnostic items taken directly from the detailed operational criteria of the IHS classification. Second, participants were required to visit their family physicians, who were requested to complete an IHS diagnosis. To assist the physician's diagnosis, an information sheet on the IHS system was provided. If the physician's diagnosis differed from the diagnosis resulting from the responses to the PAHQ, then the participant was to be excluded from the study.

In the second session, the following were collected and checked: daily cards, CAI, CSI, and doctor's letter showing diagnosis. The PAHQ was completed. Participants were requested to continue self-monitoring and were given copies of the HSES and HSLC to complete at home. At the end of the session, participants were given a tour of the psychophysiology laboratory for the purpose of pre-assessment habituation (Stern, Ray, & Davis, 1980) and instructions for attending the next session (e.g., wearing suitable clothing and not consuming vasoactive beverages in the 2-hour period before the session or any medication in the 24 hours before the session).

In the third session, the daily cards, HSES, and HSLC were collected and checked. The psychophysiological assessment was then completed. The session was divided into 15-s trials and 5-s intertrial intervals, with a block of trials defined as 10 trials. The session included four phases: (a) adaptation (2 blocks), (b) baseline (2 blocks), (c) stressor (10 blocks), and (d) post-stress recovery (2 blocks). During the adaptation, baseline and recovery phases, the word *relax* appeared on the monitor

during trials and *intertrial interval* between trials. During the stressor phase, stress was induced via difficult-to-solve anagrams accompanied by failure feedback. A different anagram was presented in each trial and participants were requested to try and solve the anagram and say the solution into a microphone during the intertrial interval. Participants were told that they would receive performance feedback in the form of statements appearing on the monitor at the end of each block of trials indicating whether their performance was below average, average, or above average on the last block of trials compared with others tested. In fact, the participants were informed that their performance was "average" on three blocks of trials and "below average" on seven blocks of trials, regardless of their actual performance. More details of this procedure are available in [Martin and Seneviratne \(1997\)](#). The session was concluded with participants completing a brief questionnaire pertaining to the session. Participants who met all the study selection criteria, including the headache measure derived from the daily cards, were then randomly allocated to the three treatment conditions.

Treatment was completed across eight 1-hour sessions scheduled weekly. This was followed by repeating the psychophysiological assessment session and brief questionnaire. Participants were debriefed at this point with respect to the false failure feedback. A final session was arranged during which participants completed a posttreatment questionnaire, LEI, CAI, CSI, HSES, and HSLC. Participants in the waiting-list control condition were offered treatment at this point. Follow-up assessments were completed 6 months and 12 months after termination of treatment. For each follow-up, participants completed daily cards

over periods of 2 weeks. Participants also completed the LEI, CAI, CSI, HSES, and HSLC.

Results

No disagreements occurred between the diagnoses resulting from responses to the PAHQ and family physicians, and hence no participants were excluded on this basis. Of the 13 participants in the waiting-list control condition, only 5 accepted the offer of treatment following the "posttreatment" assessment.

DATA PREPARATION, EXPLORATORY DATA ANALYSIS, AND ANALYTIC APPROACH

Headache pain ratings from the daily cards were averaged across the waking day to produce a composite index that reflected intensity, duration, and frequency. Medication scores (pill counts) from the daily cards were added for each day as recommended by the IHS ([IHS Committee on Clinical Trials in Tension-Type Headache, 2000](#)). The headache and medication scores were then averaged over 2-week periods at five points in time: immediately before treatment ("baseline"), mid-treatment ("treatment"), immediately after treatment ("posttreatment"), 6-month follow-up, and 12-month follow-up. Descriptive statistics for these two measures for the three conditions over the five phases of the study are shown in [Table 2](#). Inspection of the table reveals that from baseline to posttreatment, headache activity for the CBT, biofeedback, and control groups decreased by 68.3%, 55.5% and 19.9%, respectively. The equivalent figures for the medication use data were 70.3%, 41.0% and 51.9%. From baseline to 12-month follow-up, headache activity for the CBT, biofeedback, and control groups decreased by 77.3%, 50.3%, and

Table 2
Descriptive statistics for headache ratings and medication use for three treatment conditions across five phases

| Outcome measure and phase | Treatment conditions | | | | | | | | |
|---------------------------|----------------------|----------|-----------|-------------|----------|-----------|----------|----------|-----------|
| | CBT | | | Biofeedback | | | Control | | |
| | <i>n</i> | <i>M</i> | <i>SD</i> | <i>n</i> | <i>M</i> | <i>SD</i> | <i>n</i> | <i>M</i> | <i>SD</i> |
| <i>Headache ratings</i> | | | | | | | | | |
| Baseline | 18 | .911 | .759 | 19 | .732 | .550 | 13 | .679 | .667 |
| Treatment | 18 | .496 | .468 | 19 | .398 | .554 | 13 | .528 | .591 |
| Posttreatment | 18 | .289 | .346 | 19 | .326 | .469 | 13 | .544 | .571 |
| 6-Month follow-up | 12 | .328 | .436 | 13 | .322 | .267 | 9 | .322 | .388 |
| 12-Month follow-up | 10 | .207 | .225 | 11 | .364 | .506 | 8 | .434 | .737 |
| <i>Medication use</i> | | | | | | | | | |
| Baseline | 18 | 2.22 | 2.76 | 19 | 1.56 | 2.20 | 13 | 1.33 | 1.82 |
| Treatment | 18 | 1.24 | 1.66 | 19 | 0.91 | 1.71 | 13 | 0.98 | 1.25 |
| Posttreatment | 18 | 0.66 | 0.80 | 19 | 0.92 | 2.11 | 13 | 0.64 | 0.73 |
| 6-Month follow-up | 12 | 0.86 | 1.06 | 13 | 1.18 | 2.38 | 9 | 0.32 | 0.52 |
| 12-Month follow-up | 10 | 1.26 | 1.87 | 11 | 1.05 | 1.95 | 8 | 1.00 | 1.46 |

36.1%, respectively. The equivalent figures for the medication use data were 43.2%, 32.7%, and 24.8%.

Exploratory data analysis revealed significant skew in both headache pain ratings and medications scores, and given the relatively small sample size, it was felt that transformations were warranted. A range of transformations were investigated, with a reciprocal transformation resulting in the most satisfactory outcome. Further exploratory data analysis revealed no notable violation in any of the other assumptions underlying the analyses (i.e., homogeneity of variance, independence of error). The transformed measures were used in all inferential tests reported below; however, for clarity, data in the untransformed metric are reported for descriptive results.

A range of analyses were carried out. In line with current recommendations (Stevens, 2001), analysis of covariance (ANCOVA) was the analysis of choice for the main treatment outcomes. In each case, the baseline measures were entered as covariates with the immediate posttreatment measures serving as dependent variables. Follow-up pairwise group comparisons were conducted using paired-samples *t*-tests on covariate adjusted means with Bonferroni-adjusted α levels. In some cases, more focussed single degree of freedom comparisons were conducted on the same covariate-adjusted outcome measures.

To complement these analyses, split-plot ANOVAs were also conducted, with phase as the within-subjects factor and the three treatment conditions as the between-subjects factor. These analyses were particularly useful for analyzing data across the five treatment phases. While it is fully understood that the interaction term associated with these analyses is effectively an analysis of change scores, it was felt that these analyses, and in particular the simple main effects tests that followed the overall analyses, illustrated important trends in the findings.

Change scores for both headache ratings and medication use were used in the analyses related to the cognitive-behavioral and physiological moderators of treatment impact. We acknowledge the oft-cited problems associated with the use of change scores (Stevens, 2001), but as with the split-plot analyses mentioned previously, it was felt that the information derived from these analyses justified their use.

Given the relatively small sample size, particularly within treatment groups, and consequent lack of statistical power, a small number of noteworthy results with *p* levels less than .1 have been reported, provided they were associated with effect sizes of at least moderate strength. For all inferential tests, an

effect size statistic is reported (either R^2 , η^2 or *d*), along with 95% confidence intervals around the effect size (reported in parentheses after the effect size measures). In assessing magnitude of effect, we were guided by the recommendations of Hopkins (2004), who advocates that correlations of between .3 and .5 should be considered *moderate* or *medium*, with correlations of between .5 and .7 seen as *large*, *high* or *major*. For *d*, 0.2 is considered small, 0.5 is considered moderate, and 0.8 is considered large, with corresponding figures for η^2 being .01, .06, and .14 (Green & Salkind, 2005).

It should also be noted that, for the analyses reported below, no attempt has been made to correct for inflated familywise error. It was felt that such a correction would unnecessarily obfuscate the clinically and theoretically notable patterns within the findings. In evaluating these results, we would suggest the approach offered by Keppel (1991) who, in his discussion on correcting inflated familywise error, considers the scenario in which a test result would lead to the rejection of the null hypothesis at a conventional critical α level, but a failure to reject the null at the corrected α level. In these circumstances, Keppel suggests that the researcher (and reader) "suspends judgement" (p. 181). By taking such an approach, no decision is made regarding the null hypothesis; hence, a Type-1 error cannot be made, but potentially important findings are not neglected.

Before analyzing the main outcomes, a series of analyses were performed to investigate the impact of possible confounds, including headache diagnosis (migraine versus tension-type), therapist (the four therapists who delivered the interventions), and dropout (i.e., those who completed the intervention versus those who did not). A series of single-factor between-subjects ANCOVAs with baseline scores as the covariate and posttreatment scores on either headache rating or medication use as the dependent variable found no trend toward significance for the relationship between the outcome measures and either headache diagnosis, headache rating: $F(1, 47)=2.25$, $p=.14$, $\eta^2=.05$ ($<.01$, .20), medication use: $F(1, 47)=2.65$, $p=.11$, $\eta^2=.05$ ($<.01$, .21), therapist, headache rating: $F(3, 45)=0.29$, $p=.84$, $\eta^2=.02$ ($<.01$, .09), medication use: $F(3, 45)=0.29$, $p=.83$, $\eta^2=.02$ ($<.01$, .02), or dropout, headache rating: $F(1, 47)=2.11$, $p=.13$, $\eta^2=.04$ ($<.01$, .19), medication use: $F(1, 47)=1.35$, $p=.27$, $\eta^2=.03$ ($<.01$, .17).

ANALYSIS OF TREATMENT INTERVENTION

A single-factor between-subjects ANCOVA revealed a trend toward a significant difference

among the three treatment conditions on the covariate-adjusted posttreatment headache ratings, $F(2, 46)=3.06$, $p=.057$, $\eta^2=.12$ ($<.01$, $.28$), with post hoc pairwise comparisons revealing a near-significant difference between the control and CBT groups, $p=.057$. When these same data were analyzed using more focussed single degree of freedom comparisons, a significant difference with a large effect was found between the CBT and control group, $t(29)=2.42$, $p=.019$, $d=0.91$ (0.12 , 1.68), but only a trend toward significance was found between the biofeedback and control group, $t(30)=1.80$, $p=.076$, $d=0.65$ (-0.08 , 1.37). Finally, a 2 (phase: baseline, posttreatment) \times 3 (group: the three treatment conditions) split-plot ANOVA revealed a near-significant group-by-phase interaction, $\Lambda=.88$, $F(2, 47)=3.12$, $p=.054$, $\eta^2=.12$ ($.09$, $.10$), with follow-up tests of simple main effects revealing significant baseline to posttest changes for the CBT, $\Lambda=.66$, $F(1, 47)=24.03$, $p<.001$, $d=1.05$ (0.48 , 1.60), and biofeedback, $\Lambda=.80$, $F(1, 47)=12.03$, $p=.001$, $d=0.97$ (0.40 , 1.53), groups, but no significant baseline to posttreatment change for the control group.

When the data across the five phases were considered, a split-plot ANOVA revealed a significant phase-by-group interaction, $\Lambda=.51$, $F(8, 44)=2.22$, $p=.044$, $\eta^2=.29$ ($<.01$, $.38$), and follow-up tests of simple main effects on this interaction revealed a significant phase effect for both the CBT, $\Lambda=.53$, $F(4, 22)=4.98$, $p=.005$, $\eta^2=.48$ ($.07$, $.61$), and biofeedback groups, $\Lambda=.37$, $F(4, 22)=9.40$, $p<.001$, $\eta^2=.63$ ($.26$, $.73$), but only a trend toward significance for the control group, $\Lambda=.69$, $F(4, 22)=2.42$, $p=.079$, $\eta^2=.31$ ($<.01$, $.47$). Pairwise comparisons with Bonferroni-adjusted α levels on the CBT effect showed significant pairwise differences ($p<.05$, adjusted), between baseline data and each of the other phases, except the 12-month follow-up, which revealed a trend toward significance, $p=.065$. For the biofeedback group, similar comparisons revealed significant ($p<.05$, adjusted) differences between baseline data and both the treatment and posttreatment phases, and unexpected differences between the 6-month follow-up phase and both baseline and treatment. This interaction is shown in Figure 1.

The same analyses were run on the medication-use data and far fewer significant results were found. The only notable results were to emerge from the split-plot ANOVAs using both two levels of phase (baseline, posttreatment) and all five levels of phase in separate analyses. In both cases, the crucial interaction terms did not trend toward significance, but more focussed analyses of the simple main effects revealed significant baseline to

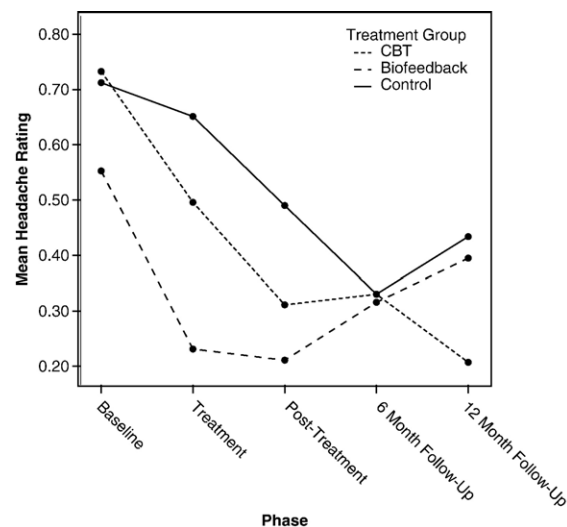


FIGURE 1 Headache ratings for three treatment groups across five phases.

posttreatment change for the CBT group, $\Lambda=.72$, $F(1, 47)=24.03$, $p<.001$, $d=0.91$ (0.35 , 1.46), and biofeedback group, $\Lambda=.909$, $F(1, 47)=5.48$, $p=.024$, $d=0.59$ (0.10 , 1.07), with no trend toward significance for the control group. Similarly, when the five phases were incorporated into a split-plot ANOVA, the phase-by-group interaction was not significant, but focussed analyses of simple main effects showed a significant phase effect for the CBT group, $\Lambda=.55$, $F(4, 22)=4.46$, $p=.009$, $\eta^2=.45$ ($.05$, $.59$), and biofeedback group, $\Lambda=.54$, $F(4, 22)=4.72$, $p=.007$, $\eta^2=.46$ ($.06$, $.60$), with no trend toward significance for the control group. Pairwise comparisons with Bonferroni-adjusted α levels on the CBT effect showed significant pairwise differences ($p<.05$, adjusted), between baseline data and the treatment and posttreatment phases, and trends toward significance between baseline figures and 6-month follow-up, $p=.06$, and 12-month follow-up, $p=.061$. These results are illustrated in Figure 2.

Finally, data were analyzed for clinically significant improvement by considering the numbers of participants in each of the three treatment conditions who demonstrated at least a 50% reduction in either headache rating or medication use (Penzien et al., 2005). For headache rating, these figures were: CBT, 14 (77.8%); biofeedback, 12 (63.2%); control, 3 (23.1%). A 2×3 χ^2 test found a significant relationship between treatment condition and whether participants reported a 50% reduction in symptoms (coded "yes" or "no"), $\chi^2(2, N=50)=9.61$, $p=.008$. The corresponding figures for the medication data were: CBT, 11 (61.1%); biofeedback, 11 (57.9%); control, 4 (36.4%), and a χ^2

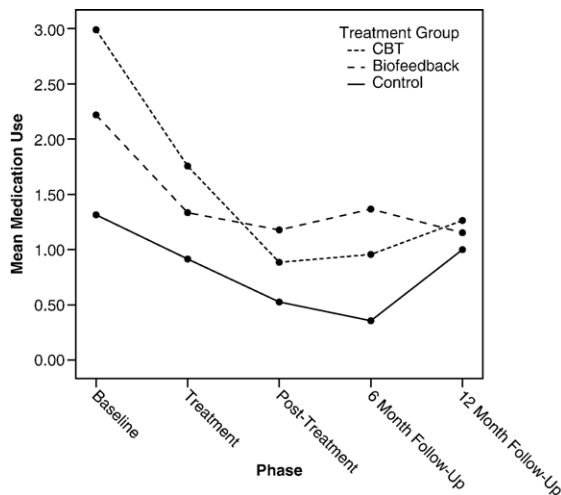


FIGURE 2 Medication use for three treatment groups across five phases.

analysis found no significant association between treatment condition and the presence of clinically significant change.

ANALYSIS OF TREATMENT MECHANISMS

In order to investigate the mechanisms underlying the treatment effects reported above, a series of correlational analyses were conducted between the main index of treatment effect, headache ratings, and three sets of variables. The measures of cognitive-behavioral skills were the three subscales of the CAI and eight subscales of the CSI. The physiological measures were divided into "tonic" measures, which were the four physiological variables (TPA, BP, HR, EMG) averaged across the baseline phase, and "phasic" measures, which were the changes in the four physiological measures from the baseline to the stressor phase. The measures of cognitive mediators were the HSES and the three subscales of the HSLC. Baseline to posttreatment change scores were used as the basic unit of analysis for all variables.

The CAI, HSES, and HSLC questionnaires, and BP, did not yield any correlations that tended to significance, and are not reported further. The top portion of Table 3 presents the notable correlations between headache ratings and the mechanism variables. The correlations indicate that for the CBT condition, improvement in headaches was associated with: (a) increased use of social support as a coping strategy; (b) increased distention of extracranial arteries at rest; (c) responding to stress after treatment with a smaller increase in the distention of the extracranial arteries, and a smaller increase in heart rate. For the biofeedback condition, improvement was associated with decreased use of social support as a coping strategy.

These relationships were tested more formally by running a series of regression models in order to examine the moderating effect of the treatment condition (CBT, biofeedback and control) on the relationship between the mechanism variables and headache ratings. For these analyses, a significant treatment group by mechanism variable interaction would indicate the presence of moderation. The only notable treatment condition by mechanism interaction to emerge was for social support coping as a predictor of headache rating change, $F(2, 31) = 3.05$, $p = .062$, $\eta^2 = .16$ ($<.01$, .36).

ANALYSIS OF PRETREATMENT PREDICTORS OF TREATMENT OUTCOME

A similar approach to the analysis of treatment mechanisms was used to analyze the relationships between baseline cognitive-behavioral and physiological variables and treatment outcome. The measures used were the subscales of the CAI and CSI and the tonic and phasic variants of the physiological variables.

The CAI and BP measures did not yield any correlations that tended to significance and are not reported further. The lower portion of Table 3 presents the important correlations between headache ratings and the cognitive-behavioral and physiological baseline measures. The correlations indicate that for the CBT treatment condition, improvement in headaches was associated with high use before treatment of problem solving, cognitive restructuring, social support, and wishful thinking as coping strategies. Improvement for this

Table 3
Selected Pearson correlations between headache ratings, proposed mechanisms, and baseline predictors

| | Treatment conditions | | | | | |
|----------------------------------|----------------------|----------|----------|-------------|----------|----------|
| | CBT | | | Biofeedback | | |
| | <i>r</i> | <i>n</i> | <i>p</i> | <i>r</i> | <i>n</i> | <i>p</i> |
| <i>Mechanisms^a</i> | | | | | | |
| Coping – Social Support | -.46 | 14 | .097 | 0.51 | 15 | 0.52 |
| Tonic TPA | -.48 | 14 | .086 | – | – | – |
| Phasic TPA | .61 | 14 | .020 | – | – | – |
| Phasic HR | .48 | 16 | .062 | – | – | – |
| <i>Baseline predictors</i> | | | | | | |
| Coping – Problem Solving | -.51 | 17 | .039 | – | – | – |
| Coping – Cognitive Restructuring | -.45 | 17 | .071 | – | – | – |
| Coping – Social Support | -.67 | 17 | .003 | – | – | – |
| Coping – Wishful Thinking | -.50 | 17 | .043 | – | – | – |
| Tonic TPA | .47 | 16 | .065 | – | – | – |
| Tonic EMG | -.48 | 14 | .086 | – | – | – |
| Phasic TPA | -.68 | 16 | .004 | – | – | – |

Note. Only correlations with $p < .1$ are presented (see text for explanation).

^a Baseline to posttreatment change scores.

group was also associated with nondistended extracranial arteries and low forehead EMG at rest and a relatively small increase in distention of extracranial arteries in response to a stressor, before treatment.

Finally, two exploratory simultaneous multiple regression analyses were conducted to investigate what proportion of the variability in headache ratings could be accounted for by combining the strongest individual physiological and cognitive-behavioral variables as predictors in separate models. Given the small sample size and the poor ratio of predictors to cases, these results must be interpreted with caution. The three physiological predictors were: tonic TPA, tonic EMG, and phasic TPA. This model was found to be a significant predictor of change in headache ratings, $F(3, 12) = 5.89$, $p = .01$, and the three measures in combination accounted for 59.6% of the sample variance. None of the individual predictors contributed significant amounts of unique predictive variance, although phasic TPA was near significant, $p = .053$, and revealed a notable squared semi-partial $r = 15.4\%$.

A similar result was found when the four strongest individual cognitive-behavioral measures were examined in the same way. The four predictors were the following coping sub-scales: Problem Solving, Cognitive Restructuring, Social Support, and Wishful Thinking. As with the previous model, these combined predictors significantly predicted change in headache ratings, $F(4, 12) = 3.62$, $p = .037$, with slightly less variance accounted for, 54.7%. Of note was the strong squared semi-partial r for the Social Support subscale, 14.2%, although neither this predictor, $p = .076$, nor any of the others contributed a significant level of unique variance.

Discussion

The CBT group showed very strong improvement and the biofeedback group slightly less impressive improvement. Participants in the CBT condition reduced headache activity by 68% and medication consumption by 70% from pre- to posttreatment. The headache reduction figure compares with the 35% to 55% improvement reported in the meta-analytic reviews (Rains et al., 2005). The control condition was also associated with decreased headache activity but the CBT condition was significantly superior, and the effect size was large (approaching 1). Headache activity in the CBT condition was lower at 12-month follow-up than immediately after treatment. Seventy-eight percent of participants in the CBT condition met the commonly used criterion for clinically significant improvement of a 50% reduction in headaches.

These results are even more impressive in the context of a treatment program of only eight sessions and an average headache chronicity in this group of 24 years.

Participants in the biofeedback condition reduced headache activity by 56% and medication consumption by 41%, from pre- to posttreatment. Although these reductions are less than for the CBT group, the decrease in headache activity still compares favorably with the 35% to 55% improvement reported in the meta-analytic reviews. The difference between the biofeedback and control groups only tended towards significance, however. The biofeedback group had the lowest headache scores posttreatment, but these scores drifted up during the follow-up period. Sixty-three percent of participants in the biofeedback condition met the criterion for clinically significant improvement.

Participants in the waiting-list control condition reduced headache activity by 20% and medication consumption by 52%, from pre- to posttreatment. This improvement in headaches was larger than would be anticipated from the literature (cf. 2% to 5% from the meta-analytic reviews). It is not clear why this occurred. The study was conducted in a rural area (Armidale, New South Wales, Australia) and country people are known to be: fiercely independent, suspicious of experts, reluctant to use government services and regard doing so as a sign of personal failure (Gething, 1997; McKenzie, 1992). Perhaps participants in the waiting-list control group felt they had to seize the initiative and do something about their headaches. This explanation is consistent with the large decrease in medication consumption. The improvement in the waiting-list control group between "posttreatment" and six-month follow-up presumably reflects five participants receiving treatment during this period.

With respect to the mechanism of CBT, there was minimal evidence in support of cognitive-behavioral skills playing a significant mediating role. There was a trend for improvement to be associated with the stress coping strategy of increased use of seeking emotional support from family and friends. Improvement in this group was associated with differences in physiological measures from pre- to posttreatment. There was a tendency for improvement to be associated with increased distention of extracranial arteries at rest, which is difficult to interpret. Improvement was significantly associated with responding to a stressor with a smaller increase in the distention of the extracranial arteries, and there was a tendency for improvement to be associated with responding to a stressor with a smaller increase in heart rate. These physiological findings are consistent with CBT leading to

participants learning to respond to a stressor with a less dysfunctional cardiovascular response.

With respect to the mechanism of biofeedback, there was no evidence in support of change in physiological variables playing a significant mediating role. Interestingly, there was a trend for improvement to be associated with using the stress coping strategy of seeking emotional support from family and friends, less; that is, the opposite trend to the one observed in the CBT condition. Perhaps improvement with biofeedback, unlike CBT, is associated with increasing autonomy and self-reliance. The hypothesized cognitive mediators (self-efficacy and locus of control) were not associated with improvement for either condition. Not surprisingly, the only mechanism variable that tended to differentiate between the CBT and biofeedback groups was using social support as a stress coping strategy.

The findings provide minimal support for the concept of giving treatment consonant with pretreatment abnormalities. Improvement with CBT was associated with high use of the coping strategies of problem solving, cognitive restructuring, social support, and wishful thinking. The first three of these strategies are considered "engagement" strategies (attempts to engage in efforts to manage the stressful person/environment transaction), whereas wishful thinking is considered a "disengagement" strategy (strategies that involve disengaging from the stressful person/environment transaction—feelings are not shared with others, thoughts about situations are avoided, and behaviors that might change the situation are not initiated). Improvement with biofeedback was not associated with any of the cognitive-behavioral measures. In summary, the only argument in favor of the treatment consonance hypothesis from the cognitive-behavioral domain is the rather weak one that CBT works well for those who engage in the "dysfunctional" coping strategy of wishful thinking, which was not the case for biofeedback.

Improvement with biofeedback was not associated with any of the physiological measures. In contrast, having nondistended arteries and low EMG at rest, and a relatively small increase in distention of the arteries from the baseline to the stressor phase, were associated with improvement via CBT. In summary, the only argument in favor of the treatment consonance hypothesis from the physiological domain, is the rather weak one that CBT does not work well for those who are physiologically "abnormal," which is not the case for biofeedback.

Rather than supporting a consonant treatment model, the analyses of predictor findings were

generally suggesting that CBT was most successful with individuals who were least "dysfunctional" from both a cognitive-behavioral and physiological perspective, whilst the analyses revealed little about predictive factors for the biofeedback group.

The final regression analyses demonstrated that the variables measured in the study predicted a significant and quite large amount of the variance in improvement for the CBT group as the combined cognitive-behavioral variables predicted 55% of the variance, and the combined physiological variables predicted 60%. The standout individual variables were social support and phasic TPA, both representing responses to stress. Headache sufferers have been shown to use social support significantly less than nonheadache controls (Holm et al., 1986), and TPA differentiates headache and nonheadache controls (Martin et al., 1992).

One notable aspect of the results was the overlap between the mechanisms analysis and predictors analysis, in terms of which variables predicted improvement with CBT. Hence, social support, tonic TPA and phasic TPA were common to both analyses. This indicates that it was individuals who scored positively on these variables (i.e., nondysfunctionally) pretreatment who did well, but it was also the individuals who made positive gains on these variables who improved most.

In summary, the CBT approach proved highly efficacious. It was particularly effective with individuals who tended to use the stress coping strategies of social support, problem solving, cognitive restructuring, and wishful thinking; and with individuals whose physiological levels at rest and in response to stress were relatively "functional."

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