Technical Review 2.2

Behavioral and Physical Treatments for Migraine Headache

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Structured Abstract

Objectives. To identify and summarize evidence from controlled trials on the efficacy of behavioral and physical treatments for migraine.

Search strategy. A strategy combining the MeSH term "headache" (exploded) and a previously published strategy for identifying randomized controlled trials was used on the January 1966 to December 1996 MEDLINE database. Other computerized bibliographic databases, textbooks, and experts were also utilized.

Selection criteria. English-language controlled trials involving patients with migraine in which at least one treatment offered was a behavioral or physical treatment were selected.

Data collection and analysis. Measures of headache index and headache frequency reported as group means (and standard deviations) were used to calculate standardized mean differences (or effect sizes). Where similar trials provided data, meta-analysis of efficacy measures was performed. The number of patients obtaining at least a 50% reduction in headache index, frequency, or severity was recorded and used to calculate odds ratios.

Main results. Behavioral treatments for migraine have a consistent body of research indicating efficacy. Summary effect sizes from a meta-analysis of 18 trials suggest that relaxation training, thermal biofeedback combined with relaxation training, electromyographic (EMG) biofeedback, and cognitive-behavioral therapy are all modestly effective in treating migraine when compared to a wait-list control. Thermal biofeedback alone or combined with cognitive-behavioral therapy yielded similar effect sizes that failed to reach statistical significance. Physical treatments have been less often studied. Six small trials of acupuncture yielded mixed results. Other physical treatments for which controlled trials have been reported include transcutaneous electrical nerve stimulation (TENS) (2 trials), cervical mobilization and manipulation (1 trial), occlusal adjustment (1 trial), and hyperbaric oxygen (1 trial).

Conclusions. Each of the behavioral therapies considered has modest efficacy for migraine. There is little information about which patients will benefit from particular behavioral approaches; the choice among them may, for the present, depend more on availability and acceptability than on data about efficacy. There are insufficient data about any of the physical treatments to draw conclusions about their efficacy.

Contents

Summary

Introduction

Background

Migraine is a common and disabling health problem among adult Americans. Surveys from the U.S. and elsewhere suggest that 6% of men and 15% to 17% of women experience migraine headaches. These headaches result in significant disability and work loss; estimated aggregate indirect costs to employers in the U.S. for reduced productivity due to migraine range from $6.5 billion to $17 billion annually. Even these measurements fall short of demonstrating the full impact of migraine on the individual and society because they fail to account for the substantial effect of migraine on other aspects of life.

There is now a broad array of drug therapies for the acute and preventive treatment of migraine, and almost all migraine sufferers have used drugs at one time or another to treat their headaches. But pharmacological treatments are not suitable for all patients, nor are they universally effective. Partly for these reasons, there is growing interest among patients and health care providers in alternative treatments for migraine, including behavioral and physical treatments.

Several behavioral treatments have been widely used over the past two decades in the management of recurrent migraine. The most frequently employed interventions fall into three broad categories: relaxation training, biofeedback training (often administered in conjunction with relaxation training), and cognitive-behavioral (or stress-management) therapy. Over the same period of time, there has also been an increase in the use of physical treatments for migraine, principally acupuncture, cervical manipulation, and mobilization therapies. Though there are exceptions, these behavioral and physical interventions are primarily aimed at the prevention of migraine episodes rather than the alleviation of symptoms once an attack has begun.

If effective and available, these non-pharmacological treatments may be the first choice for most patients and may also be well suited for the significant minority of migraine patients who: (a) have poor tolerance of pharmacological treatments; (b) have medical contraindications for pharmacological treatments; (c) experience insufficient relief from, or are unresponsive to, pharmacological treatment; (d) wish to become pregnant (or are nursing); (e) have a history of long-term, frequent, or excessive use of analgesic or abortive medications that can aggravate headache problems; and (f) simply prefer to avoid medication use.

Scope of Evidence Report

The objective of this evidence report is to provide a comprehensive review and analysis of published reports of randomized controlled trials (RCTs) and other prospective, comparative clinical trials of behavioral and physical treatments for migraine. The report is limited to therapies that have been studied specifically among

populations of patients with migraine. As a result, some treatments used by health care providers to treat migraine may not be represented.

Methodology

The literature review addressed the question "What are the *effects on headache pain and/or headache frequency* when behavioral (physical) treatments are compared to no intervention (wait-list control), "placebo" or sham interventions, alternative behavioral or physical treatments, and drug therapies among patients with migraine headache?" (A "wait-list control" is a group of patients who receive no treatment during the trial but who will be treated once the trial ends. This group therefore serves as a "control" with which to compare results from groups that do receive active treatment.)

To be considered for this review, studies were required to be prospective, controlled trials of behavioral or physical treatments aimed at the prevention of attacks of migraine headache or the relief of symptoms of individual episodes of headache in patients with migraine. Behavioral treatments considered included the broad categories of relaxation, biofeedback, cognitive-behavioral (or stress-management) therapy, and hypnosis. Physical interventions considered included acupuncture, cold and heat therapies, ultrasound, transcutaneous electrical nerve stimulation (TENS), trigger point intervention, occlusal adjustment, cervical manipulation, mobilization therapy, exercise, diet, and hyperbaric oxygen therapy.

Although the use of a specific set of diagnostic criteria (e.g., those developed by the Ad Hoc Committee on the Classification of Headache and the Headache Classification Committee of the International Headache Society [IHS]) was not required, diagnoses were required to be based on at least some of the distinctive features of migraine, e.g., nausea/vomiting, severe head pain, throbbing character, unilateral location, phono/photophobia, or aura. As the IHS criteria allow, we considered patients described as having "mixed" migraine and tension-type headache or "combination" headache to have migraine.

Studies were included only if allocation to treatment groups was randomized or quasi-randomized (based on some non-random process unrelated to the treatment selection or expected response); concurrent cohort comparisons and other non-experimental designs were excluded. Control groups could comprise no intervention, placebo or sham interventions, usual care, or a specified alternative drug or non-drug treatment.

Relevant controlled trials were identified by searching MEDLINE (January 1966 through December 1996) using the MeSH term "headache" (exploded) and a published strategy for identifying randomized controlled trials. Additional search strategies included computerized bibliographical searching of PsycINFO and CINAHL databases; retrospective and prospective hand-searching of the journals *Headache*, *Cephalalgia*, and *Headache Quarterly* from the inception of each (1981, 1961, and 1990, respectively); searching the reference lists of review articles and included studies; searching books related to headache; and consulting experts in the field. We also searched a database of randomized trials in pain relief which is now part of the Cochrane Controlled Trials Register.

Studies identified by the literature search were screened for further review based on criteria focusing on patient population, intervention, study design, and type of outcome data reported.

Studies passing the initial screen were reviewed for methodological quality based on the following considerations: the use of random allocation; description of an adequate method of concealment of allocation; the use of double-blinding; description of an adequate method of blinding; and a description of drop-outs sufficient to determine the number of patients in each treatment group entering and completing the trial. Each trial could score 1 point for each criterion (for a total of from 0 to 5 points), with higher scores indicating higher quality in the conduct or reporting of the trial.

Efficacy data were abstracted from the original reports on to specially designed forms. We collected trial data on symptomatic outcomes related to head pain (frequency, severity/intensity, and duration) and other symptoms of migraine (nausea, vomiting, photophobia, phonophobia). Secondary outcomes recorded included medication use, functional status (disability), and quality of life. We did not consider physiological or other measures not directly relevant to the patients' symptomatic experience.

We preferred that outcome data be based on daily recording of headache symptoms by patients, rather than on global or retrospective assessments performed by patients or investigators. Outcomes were recorded post-treatment and at follow-up, if available.

We preferred combined measures of headache symptoms such as headache indexes (variously defined combinations of frequency, intensity, and duration). In the absence of a headache index, we recorded headache frequency alone. If neither headache index values nor frequency data were reported, we analyzed data on headache intensity.

For dichotomous outcomes (e.g., success/failure), we required that the threshold for distinguishing between success and failure be clinically significant; for example, we interpreted a 50% or more decrease in headache frequency or headache index (two of the most common definitions) as meeting this criterion. Dichotomous outcomes meeting our definition of a clinically significant threshold were reported as proportions (or response rates for each treatment) which may be directly compared (difference in proportions). We also used these proportions to calculate odds ratios in the case of the physical treatment trials.

In the few instances in which outcome data were reported on an ordinal scale (e.g., for reduction in headache frequency: none, some, moderate, significant, very significant), we selected a threshold based on the definition of clinically significant improvement (discussed above) and converted these data into a dichotomous outcome.

Most of the behavioral treatment trials and a few physical treatment trials reported outcomes on a continuous scale (e.g., mean headache index or mean headache frequency). In these cases, whenever variance estimates were also available, we re-scaled and standardized the continuous outcome data for each treatment condition in each study using a published method. In the case of the behavioral trials, we then used the resulting standardized outcome measures to calculate summary effect sizes for each type of treatment, using a multi-variable, random-effects model, controlling for study. For the purposes of this meta-analysis, the behavioral interventions were grouped into categories based in part on statistical considerations and in part on clinical considerations.

Because some of the behavioral trials that reported continuous data did not permit effect size calculation, the sample of studies included in the meta-analysis may be subject to bias. To investigate this potential bias, we calculated another measure of

effectiveness, the percentage of improvement (in headache index or frequency) from pre- to post-treatment. Because large differences between the percentage improvement scores from studies *included in the meta-analysis* and those from studies *excluded from the meta-analysis* would suggest bias, we compared the mean percentage improvement scores (weighted for sample size) of the two groups.

We also used the standardized outcome measures described above to calculate individual effect sizes for pair-wise comparisons of active behavioral treatments with control treatments for every trial with a control arm; and to calculate effect sizes for all pair-wise comparisons in the only trial of physical treatments for which effect sizes could be calculated.

Throughout the report, wherever we have used the word "significant" to describe results, we mean "statistically significant at an alpha level of 0.05 for the two-sided alternative hypothesis." Wherever we have reported on results that are clinically, rather than statistically, significant, we have explicitly used the word "clinically."

Findings

Behavioral Treatments

Thirty-nine trials of behavioral treatments were included in the report; eighteen of these reported continuous outcome data and variance data and were included in a meta-analysis. The principal findings of our analysis were:

- Behavioral treatments for migraine have a consistent body of research indicating efficacy. The effect size data suggest that relaxation training, thermal biofeedback combined with relaxation training, electromyographic (EMG) biofeedback, and cognitive-behavioral therapy are all modestly effective in treating migraine when compared to wait-list control. Trials using thermal biofeedback alone yielded an effect size point estimate similar to these treatments, but the estimate was not statistically significant, perhaps because only three studies contributed data. Trials of thermal biofeedback combined with cognitive-behavioral therapy also yielded an effect size that failed to reach statistical significance, though the point estimate was not higher than that for cognitive-behavioral therapy alone and fairly similar to those for other treatments involving thermal biofeedback.
- A large number of studies could not be included in the meta-analysis because they did not report variance data, even though they met all other inclusion criteria. Comparison of percentage improvement scores from trials included in, and excluded from, the meta-analysis did not substantially change our interpretation of the effect-size data.
- The results of the meta-analysis provided little guidance for choosing among the treatments considered.
- Inconclusive results were reported on the following topics: whether there is an incremental benefit to adding one type of behavioral therapy to another; comparisons of behavioral therapies and drug treatments for migraine; and the relative efficacy of different methods of delivering behavioral therapies (home- vs. clinic-based treatment, standard vs. minimal therapist contact therapy, standard vs. standard + booster treatments).

Physical Treatments

Eleven controlled trials of physical treatments were reviewed. The main findings were as follows.

- Six small trials of *acupuncture* yielded mixed results. A single study using a wait-list control (no intervention) failed to find a significant result. Two trials comparing acupuncture to sham acupuncture in a single-blind fashion found a statistically significant benefit to genuine acupuncture. A single trial comparing acupuncture with sham TENS found no significant difference between the two interventions. None of the trials comparing acupuncture to active pharmacological or behavioral treatments found acupuncture to be clinically or statistically significantly better than the comparator.
- Two trials of *TENS* provided little support for the effectiveness of this treatment for migraine.
- One trial compared *three manual interventions*: a control group (cervical mobilization), cervical manipulation performed by a medical practitioner or physiotherapist, and cervical manipulation performed by a chiropractor. The results provided little support for the use of manipulation or mobilization in patients with migraine.
- A single trial of *occlusal adjustment* among patients with migraine and mixed migraine and tension-type headaches found no significant effect among migraine patients and a modest, but statistically significant, effect among mixed headache patients.
- One small pilot study of *hyperbaric oxygen* for the treatment of acute migraine suggested a large effect. However, even if further research were to verify these results, the rare availability and high cost of the equipment involved would limit the clinical application of this treatment.

Future Research

Further research is required into the efficacy of currently available physical and behavioral treatments if their use for migraine is to be optimized. The following recommendations may be made.

Conduct and Reporting of Trials

1. The diagnosis of migraine—even when made according to specific criteria such as the IHS criteria for migraine with aura and migraine without aura—encompasses a wide range of symptomatology. Researchers should be as precise as possible in describing any operational inclusion or exclusion criteria they employ in addition to headache diagnosis, such as headache frequency, severity, and chronicity. Furthermore, researchers should state whether patients with co-existing tension-type headache were excluded. In addition to describing the inclusion and exclusion criteria applied, researchers should describe the relevant characteristics among the population actually enrolled.
2. Comparisons using recruitment from well-described clinical populations such as primary care practices or managed care organizations should be performed to expand the generalizability of the results reviewed in this report.
3. Future studies should include extended periods of follow-up for patients receiving behavioral or physical treatments and control subjects to evaluate the long-term effectiveness of such treatments.
4. There was tremendous variety in the way patients respond to the treatments reviewed in this report. Individual

trials may not be able to identify patient characteristics that may predict a positive response to one treatment or another, but if trials were to report individual patient data, meta-analysis of such trials might have sufficient power to do this. Better data on predictors of good response to behavioral and physical treatments may help to select patients most likely to benefit from these treatments.

5. Adoption of certain standards recommended by the International Headache Society would strengthen the validity and comparability of trials of physical and behavioral treatments; these standards include:
   a. Use of a prospective baseline period of at least 1 month;
   b. Use of a treatment period of at least 3 months;
   c. Use of a daily headache diary;
   d. Use of frequency of attacks per 4 weeks as main efficacy parameter rather than headache index or other measures; and
   e. Use of a 50% reduction in attack frequency compared with baseline as the criteria for individual response.

Future Research Directions

Physical Treatments

6. Research needs to be conducted to fill important gaps in the literature on physical treatments for migraine. None of the physical treatments has a sufficient body of evidence from which to draw firm conclusions about efficacy for migraine. Frequently-used physical treatments such as massage or mobilization therapy have not been tested at all against appropriate controls.
7. Sham acupuncture may result in opioid and other neuromediator changes in central nervous system and immune system cells, and may therefore be an inappropriate active control for studies of acupuncture. Although the Office of Alternative Medicine of the National Institutes of Health (NIH) does not recommend use of double-blinding in studies of acupuncture, research on the effect of various sham acupuncture techniques should be performed to develop an empirical basis for selecting an acceptable control treatment.

   We note that NIH has recently targeted acupuncture as a priority for research funding. The NIH issued a program announcement in February 1998 to support pilot studies to establish the methodological feasibility of and to strengthen the scientific rationale for proceeding to full-scale RCTs on the use of acupuncture to prevent, manage, or treat various symptoms/disorders. The emphasis of this program is on developing an appropriate study design rather than on attempting to complete insufficiently powered trials.

Behavioral Treatments

8. Further research needs to be conducted comparing behavioral and drug treatments for migraine and exploring possible combinations of these therapies. This type of research may have been hampered in the past by the fact that behavioral and drug therapies are usually provided, institutionally, by different professionals.
9. Research is also needed on acceptable control treatments for studies of behavioral treatments.
10. A number of behavioral treatments have provided evidence that they are effective. To help the largest number of patients possible, it would be

beneficial to obtain more information about the optimal order or combination of those treatments.

11. More collaborative and multi-site studies of behavioral trials are needed. Much of the research on behavioral therapies has been performed at a relatively small number of centers by a few investigators and their trainees. The complex and subjective nature of much of the training leads to questions about whether the results observed with these interventions can be reproduced in other practice settings.

Technical Review

Introduction

Background

Migraine is a common and disabling health problem among adult Americans. Surveys from the U.S. and elsewhere suggest that 6% of men and 15% to 17% of women experience migraine headaches (Stewart, Shechter, and Rasmussen, 1994). These headaches result in significant disability and work loss; estimated aggregate indirect costs to employers in the U.S. for reduced productivity due to migraine range from $6.5 billion to $17 billion annually (Osterhaus, Gutterman, and Plachetka, 1992). Even these measurements fall short of demonstrating the full impact of migraine on the individual and society because they fail to account for the substantial effect of migraine on other aspects of life (Stewart, Shechter, and Lipton, 1994).

There is now a broad array of drug therapies for the acute and preventive treatment of migraine, and almost all migraine sufferers have used drugs at one time or another to treat their headaches. But pharmacological treatments are not suitable for all patients, nor are they universally effective. Partly for these reasons, there is growing interest among patients and health care providers in alternative treatments for migraine, including behavioral and physical treatments.

Several behavioral treatments have been widely used over the past two decades in the management of recurrent migraine. The most frequently employed interventions fall into three broad categories: relaxation training, biofeedback training (often administered in conjunction with relaxation training), and cognitive-behavioral (or stress-management) therapy. Over the same period of time, there has also been an increase in the use of physical treatments for migraine, principally acupuncture, cervical spinal manipulation, and mobilization therapies. Though there are exceptions, these behavioral and physical interventions are primarily aimed at the prevention of migraine episodes rather than the alleviation of symptoms once an attack has begun.

If effective and available, these non-pharmacological treatments may be the first choice for most patients and may also be well suited for the significant minority of migraine patients who: (a) have poor tolerance of pharmacological treatments; (b) have medical contraindications for pharmacological treatments; (c) experience insufficient relief from, or are unresponsive to, pharmacological treatment; (d) wish to become pregnant (or are nursing); (e) have a history of long-term, frequent, or excessive use of analgesic or abortive medications that can aggravate headache problems; and (f) simply prefer to avoid medication use.

Objectives and Organization of the Report

The objective of this evidence report is to provide a comprehensive review and analysis of published reports of RCTs and other prospective, comparative clinical trials of behavioral and physical treatments for migraine. The report is limited to therapies that have been studied specifically among populations of patients with migraine. As a result, some treatments used by health care

providers to treat migraine may not be represented.

The report is organized into two sections, one on behavioral therapies and one on physical treatments for migraine. Within each section, the text briefly describes the studies identified by the literature review, summarizes the evidence for efficacy, and draws conclusions. A general discussion and conclusion, a description of future research needs, and a list of references are provided at the conclusion of the two main sections.

Evidence Tables 1, 2, 3, and 4 provide concise information from the included studies. Evidence Tables 1 and 3 summarize the studies included in the analysis of behavioral and physical treatments, respectively, describing in a standardized way the design of each study; characteristics of the patient population; headache diagnostic criteria used; inclusion and exclusion criteria related to headache characteristics; interventions; treatment protocols; outcomes measured; and results. Evidence Tables 2 and 4 summarize the evidence for the efficacy of behavioral and physical treatments, respectively.

We were able to perform a meta-analysis of the main results from the behavioral treatment trials; the results of that meta-analysis are described in the text of the section on behavioral treatments. It was not possible to combine results from the much smaller number of studies of physical treatments in a meta-analysis; results from those trials are described on a more individual basis in the section on physical treatments.

Methodology

Topic Questions

The topic questions addressed in the literature review were:

1. What are the *effects on headache pain and/or headache frequency* when behavioral treatments are compared to no intervention (wait-list control), "placebo" or sham interventions, alternative behavioral or physical treatments, and drug therapies among patients with migraine headache? (A "wait-list control" is a group of patients who receive no treatment during the trial but who will be treated once the trial ends. This group therefore serves as a "control" with which to compare results from groups that do receive active treatment.)
2. What are the *effects on headache pain and/or headache frequency* when physical treatments are compared to no intervention (wait-list control), "placebo" or sham interventions, alternative physical or behavioral treatments, and drug therapies among patients with migraine headache?

Criteria for Considering Studies for This Review

To be considered for this review, studies were required to be prospective, controlled trials of behavioral or physical treatments aimed at the prevention of attacks of migraine headache or the relief of symptoms of individual episodes of headache in patients with migraine. Studies were included only if allocation to treatment groups was randomized or quasi-randomized (based on some non-random process unrelated to the treatment selection or expected response); concurrent cohort comparisons and other non-experimental designs were excluded. Control groups could comprise no intervention, placebo or sham intervention, usual care, or a specified alternative non-drug or drug treatment.

Search Strategy for Identification of Trials

Relevant controlled trials were identified by MEDLINE searches using the

MeSH term "headache" (exploded) and the search strategy for identifying randomized controlled trials described by Dickersin, Scherer, and Lefebvre (1994) (see Appendix A). The MEDLINE searches included literature indexed from January 1966 through December 1996. Additional search strategies included computerized bibliographical searching of PsycINFO and CINAHL databases; retrospective and prospective hand-searching of the journals *Headache*, *Cephalalgia*, and *Headache Quarterly* from the inception of each (1981, 1961, and 1990, respectively); searching the reference lists of review articles and included studies; searching books related to headache; and consulting experts in the field. We also searched a database of randomized trials in pain relief which is now part of the Cochrane Controlled Trials Register (1997).

Results of Search

Searches of all sources retrieved a total of 6,660 articles (including 352 review articles) on the diagnosis, treatment, and cost of chronic headache (migraine, tension-type, and other types of primary headache). Of these, 2,106 were judged to merit scrutinizing the complete article. Of the articles reviewed, 1,085 concerned the treatment of chronic headache (rather than diagnosis or cost), and 335 of these articles included at least one behavioral or physical treatment arm. Of the 335 behavioral and physical treatment articles reviewed, 88 met all the criteria for consideration in the evidence report (i.e., they were controlled trials conducted on a non-pediatric population of patients with migraine). Seventy-five publications reporting on 70 separate controlled trials concerned behavioral therapies for migraine, and 13 publications reporting on 12 separate controlled trials concerned physical treatments for migraine.

Initial Screening and Data Abstraction

Studies identified by the literature search were screened for further review based on criteria focusing on patient population, intervention, study design, and type of outcome data reported. The screen was performed by research nurses specially trained in the application of these criteria, who demonstrated good inter-rater reliability. We found excellent inter-rater reliability (kappa=0.95; 95% confidence interval: 0.73 to 1.0) among the three screeners following training; excellent reliability was maintained in subsequent periodic monitoring during the screening process.

The initial screen was based upon the criteria for considering studies for the review and were implemented as lists of keywords that described specific examples to include or exclude. For example, for "patient type," the general rule was that we would accept studies of adults with headache syndromes. This rule was supplemented with lists of appropriate and inappropriate keywords such as the following: headache not otherwise specified, migraine, tension-type headache, tension headache, etc. Excluded were keywords such as "post-lumbar puncture headache." In response to reviewers' questions, the criteria were updated periodically throughout the selection process, based upon titles and abstracts actually reviewed. The list of screening criteria is several pages long. Because these criteria applied to the overall headache project and not expressly to this report, they are not included here.

Studies passing the initial screen were reviewed for methodological quality (see below). Efficacy data were abstracted from the original reports onto specially designed forms (see Appendix B) by the same research nurses who performed the initial screen. During the data abstraction process,

the source of extracted data was indicated on the original published report using a highlighter and handwritten notes. The annotated published report was paired with the data abstraction form, and these were kept together during the remainder of the data management and analysis process. When statistical analyses were performed, key data elements were verified on the original report.

Evaluation of Methodological Quality of Individual Trials

We assessed the internal validity of individual trials using a scale devised by Jadad, Moore, Carroll, et al. (1996). This scale evaluates methodological quality based on the following considerations: the use of random allocation; description of an adequate method of concealment of allocation; the use of double-blinding; description of an adequate method of double-blinding; and a description of drop-outs sufficient to determine the number of patients in each treatment group entering and completing the trial. These criteria were applied during data abstraction using the standardized form reproduced in Exhibit 1 (see also the data collection form in Appendix B, which incorporates this instrument). Each trial could score 1 point for each criterion (for a total of from 0 to 5 points), with higher scores indicating higher quality in the conduct or reporting of the trial.

Each of the items on this quality scale is an accepted criterion that has been empirically validated. The Jadad instrument is one of only a few such scales that has undergone a formal process of development and demonstrated good inter-rater reliability (Moher, Jadad, Nichol, et al., 1995).

It is impossible to perform most behavioral and physical treatments in a blinded fashion. Notable exceptions include studies of biofeedback using true versus sham feedback, in which double blinding is possible; and studies of acupuncture using true versus sham acupuncture, in which single-blinding only is possible.

The score assigned to each trial is described in Evidence Tables 1 and 3. Components of the score have been noted as follows:

Either "not randomized" *or* "randomized," with a "+" after "randomized" if the method of randomization was described and was adequate, and a "-" after "randomized" if the method of randomization was described, but was inadequate.

Either "not double-blind" *or* "double-blind," with a "+" after "double-blind" if the method of blinding was described and was adequate, and a "-" after "double-blind" if the method of blinding was described, but was inadequate.

Either "no description of dropouts" *or* "dropouts described."

Thus, for example, a trial that was explicitly described as "randomized" would receive 1 point; if it did not provide a description of the methods for generating the sequence of randomization, it would not receive a point (0 points); if it was explicitly described as double-blinded, it would receive 1 point; if it provided a description of an adequate method of blinding, it would receive another 1 point (designated with a "plus" sign); if it did not describe dropouts or withdrawals (and we could not determine them from the number of patients included in the efficacy analyses), the study would not receive a point (0 points). This hypothetical trial, therefore, would receive a quality score of "3" and would be described in the Evidence Table as "randomized, double-blind+, no description of dropouts."

Exhibit 1. Instrument to measure the likelihood of bias in pain research reports*

	Question	Response	Score
1	Was the study described as **randomized** (this includes the use of words such as randomly, random and randomization)?	Yes No	1 0
1a	If the method of generating the sequence of randomization was described, was it **adequate** *(table of random numbers, computer-generated, coin tossing, etc.)* or **inadequate** *(allocated alternately, according to date of birth, hospital number, etc.)*?	Not described/NA Adequate Inadequate	0 1 -1
2	Was the study described as **double-blind**?	Yes No	1 0
2a	If the method of blinding was described, was it **adequate** *(identical placebo, active placebo, dummy, etc.)* or **inadequate** *(comparison of tablet vs. injection with no double dummy)*?	Not described/NA Adequate Inadequate	0 1 -1
3	Was there a description of **withdrawals** and **drop-outs**?	Yes No	1 0

*Adapted from *Controlled Clinical Trials* 17(1), Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, McQuay HJ. Assessing the quality of reports of randomized clinical trials: is blinding necessary? (pp. 1-12), copyright 1996, with permission from Elsevier Science.

Types of Participants

Subjects were required to meet reasonable criteria designed to distinguish migraine from tension-type headache; if patients with migraine and patients with tension-type headache were included in the same trial, results had to be stratified by headache diagnosis. Although the use of a specific set of diagnostic criteria (e.g., Ad Hoc Committee on the Classification of Headache, 1962; Headache Classification Committee of the International Headache Society, 1988) was not required, diagnoses were required to be based on at least some of the distinctive features of migraine, e.g., nausea/vomiting, severe head pain, throbbing character, unilateral location, phono/photophobia, or aura. Furthermore, secondary headache disorders had to be excluded using reasonable criteria. No further restrictions were placed on studies regarding particular inclusion or exclusion criteria relating to the frequency, duration, or severity of migraine headaches.

Many of the trials reviewed in this report included patients described as having "mixed" migraine and tension-type headaches or "combination" headaches. It was not always clear whether these descriptions referred to patients who had discrete episodes of migraine and discrete episodes of tension-type headache, or to patients with headaches which (in the view of the investigators) combined features of migraine and tension-type headache. As the IHS criteria allow, we considered patients in either of these categories to have migraine. Wherever separate results were reported for migraine and "mixed" or "combination" patients, we described and analyzed these results separately. Trials and

treatment groups including only patients with tension-type headache were excluded from consideration.

Types of Interventions

Studies were required to have at least one arm that used a behavioral or physical treatment for migraine. Provided that one treatment arm in a trial met this criterion, comparator groups could comprise no intervention, sham interventions (placebo), other behavioral or physical treatments, or preventive or acute drug therapies.

Behavioral Interventions

The behavioral treatments considered for this report included the broad categories of relaxation, biofeedback, cognitive-behavioral (or stress-management) therapy, and hypnosis.

Relaxation techniques considered included those that train patients to control muscle tension and those that teach patients to use mental relaxation and/or visual imagery to achieve treatment goals. The main techniques considered were:

1. Progressive muscle relaxation (PMR)—alternately tensing and relaxing selected muscle groups throughout the body (Bernstein and Borkovec, 1973);
2. Autogenic training—the use of self-instructions of warmth and heaviness to promote a state of deep relaxation (Schultz and Luthe, 1969); and
3. Meditation or passive relaxation—the use of a silently repeated word or sound (Benson, 1975) or guided imagery to promote mental calm and relaxation.

We considered only those techniques that involve at least some formal training by a therapist. Methods using unsupervised book or tape instruction were excluded.

The biofeedback techniques considered were standard thermal (hand-warming) and electromyographic biofeedback. We did not consider biofeedback techniques that are non-standard, technically difficult, or clinically unavailable in the U.S., such as galvanic skin response, blood volume pulse biofeedback, cephalic vasomotor biofeedback, and techniques requiring photoplethysmography. We also excluded experimental conditions that were designed to assess the mechanism of a biofeedback therapy, particularly those in which subjects were trained in a skill opposed to that theoretically required for therapeutic effects, for example, those training subjects to increase EMG activity or decrease hand temperature. In order to be considered, biofeedback training had to involve formal training by a therapist.

Treatments considered under the heading of cognitive-behavioral therapy were those involving a psychotherapeutic intervention which had as its primary goal the teaching of skills for identifying and controlling stress and the effects of stress. Such interventions were variously described in the literature as cognitive-behavioral therapy, cognitive therapy, and stress-management training.

The only hypnotic treatments considered were those in which hypnotic induction and suggestion were primarily aimed at headache control.

Interventions that combined two or more of these techniques were also considered. The combination of biofeedback and relaxation training was especially common.

Physical Interventions

Physical interventions considered for this report included acupuncture, cold and heat therapies, ultrasound, TENS, trigger point intervention, occlusal adjustment, chiropractic manipulation, mobilization therapy, exercise, diet, and hyperbaric oxygen therapy.

We considered both classical and non-classical acupuncture, with or without electrical stimulation. Occlusal adjustment

was considered only when it was used on patients with a primary diagnosis of headache and when headache outcomes were primary. Manipulation was defined, for the purposes of this review, as any short- or long-lever, high velocity thrust directed to one or more of the joints of the cervical spine. Manipulative techniques normally involve moving a joint beyond its normal range of motion. Mobilization, by contrast, includes any other manual therapy involving movement of a joint within its normal range of motion and directed at joint dysfunction or soft tissues; it thus includes massage and stretching.

Control Treatments

Control treatments included wait-list or other no-intervention controls and placebo or sham treatment controls. In order to be included in the analysis, wait-list or no-intervention controls were required to have received neither placebo nor active treatment for their headaches, but must have been evaluated in the same manner as the patients receiving active treatment (e.g., by completing daily recordings of headache activity).

Outcome Definitions

Most of the interventions considered in this report are preventive in aim, i.e., they focus on reducing the frequency and/or intensity of recurrent migraine headaches and not on aborting or relieving individual acute episodes. We collected trial data on symptomatic outcomes related to head pain (frequency, severity/intensity, and duration) and other symptoms of migraine (nausea, vomiting, photophobia, phonophobia). Secondary outcomes recorded included medication use, functional status (disability), and quality of life. We did not consider physiological or other measures not directly relevant to the patients' symptomatic experience.

We preferred combined measures of headache symptoms such as headache indexes (variously defined combinations of frequency, intensity, and duration). In the absence of a headache index, we recorded headache frequency alone. Studies have shown that headache frequency is significantly correlated with both headache intensity and duration (Penzien, Johnson, Seville, et al., 1994). If neither headache index values nor frequency data were reported, we analyzed data on headache intensity.

Specific Requirements for Outcome Data

Source and Nature of Data

We preferred that outcome data be based on daily recording of headache symptoms by patients themselves, rather than on global or retrospective assessments performed by patients or investigators. Trials reporting only the latter type of outcome data were not included in the behavioral meta-analysis.

Timepoints Considered

Outcomes were recorded post-treatment and at follow-up, if available. Post-treatment was considered to be between 8 and 12 weeks after the start of treatment or immediately following the end of treatment, whichever was later. We considered follow-up data to be that recorded at the last available timepoint for which the drop-out rate was less than 20% and for which data were reported for all treatment groups.

Use of Preventive and Acute Medication

Many trials permitted the use of medication for acute migraine attacks experienced during the trial period, and some included patients taking preventive medication. We recorded descriptions of trial rules concerning the use of preventive and acute medication in Evidence Tables 1 and 3 whenever such information was provided in the studies. We did not

otherwise model or adjust for this factor in the analysis.

Analysis of Dichotomous Data

Some studies reported treatment success and failure as a dichotomous outcome. In such cases, we required that the threshold for distinguishing between success and failure be clinically significant; for example, we interpreted a 50% or more decrease in headache frequency or headache index as meeting this criterion.

Dichotomous outcomes meeting our definition of a clinically significant threshold were reported in Evidence Tables 2 and 4 as proportions (or response rates for each treatment) which may be directly compared (difference in proportions). For those physical treatment trials that reported outcomes in dichotomous form, we also used these proportions to calculate odds ratios (Fleiss, 1981). An odds ratio estimate of 1 indicates "even odds" or no treatment effect, while an odds ratio greater than 1 indicates greater likelihood of improvement with the tested treatment than the comparator. The 95% confidence interval for the odds ratio can be interpreted as a test of statistical significance; if the confidence limit excludes 1 (null effect), then the treatments are significantly different. The odds ratio is a relative measure of efficacy and should be interpreted along with the response rates and the difference in response rates between groups. The odds ratio approximates the risk ratio at low event rates; however, the response rates among headache studies are high enough so that there are large differences between the odds ratio and risk ratio, with the odds ratio overestimating risk ratio substantially.

Most of the behavioral treatment trials we reviewed reported continuous outcome data, rather than dichotomous or ordinal; our meta-analysis of those trials was accordingly based on the continuous data. We did not calculate odds ratios for the few behavioral trials that reported dichotomous outcome data. We did, however, report the proportion of patients meeting the definition of clinical success in each of these trials in Evidence Table 2, as indicated above.

Analysis of Ordinal Data

In the few instances in which outcome data were reported on an ordinal scale (e.g., for reduction in headache frequency: none, some, moderate, significant, very significant), we selected a threshold based on the definition of clinically significant improvement (discussed above) and converted these data into a dichotomous outcome.

Analysis of Continuous Data

General

For outcomes reported on a continuous scale (e.g., mean headache index or mean headache frequency), we identified pre- and post-treatment group mean scores wherever possible. When variance data were also reported, these pre- and post-treatment group mean scores were re-scaled and standardized for each treatment condition in each study, as described by Hasselblad (1998). The resulting standardized outcome measures were used to:

1. Calculate summary effect sizes for each type of treatment considered in the meta-analysis of the behavioral trials;
2. Calculate effect sizes for pair-wise comparisons of active behavioral treatments with control treatments for every trial with a control arm; and
3. Calculate effect sizes for all pair-wise comparisons in the only trial of physical treatments for which effect sizes could be calculated.

Each of these analytical procedures is described in greater detail below.

Many trials reported pre- and post-treatment group means, but did not report data on the variance associated with these

means. In such cases, we attempted to calculate or estimate variances based on primary data or test statistics, if these were reported.

When a trial used pre- and post-treatment scores to calculate a change score for each patient and used these within-patient change scores to calculate a group mean change score, then we used these group mean change scores. When only post-treatment data were available for each treatment group, we used these data, relying on allocation to achieve between-group balance.

Finally, whenever a trial reported both pre- and post-treatment group mean scores, these were used to estimate the percentage improvement, as a separate outcome measure, for each treatment group. The percentage improvement scores are uncontrolled; that is, the percentage improvement is calculated for each treatment arm based upon pre- and post-treatment scores, without regard to observed improvement in other treatment arms in the same study.

Throughout the report, wherever we have used the word "significant" to describe results, we mean "statistically significant at an alpha level of 0.05 for the two-sided alternative hypothesis." Wherever we have reported on results that are clinically, rather than statistically, significant, we have explicitly used the word "clinically."

Meta-Analysis of Behavioral Trials

As stated above, whenever pre- and post-treatment group means *and* variance data were available, we re-scaled and standardized the group mean scores for each treatment condition in each study, as described by Hasselblad (1998). We then included the resulting re-scaled and standardized outcome measures from individual studies in a multi-variable, random-effects model to estimate a summary effect size for each type of treatment, controlling for study (Hasselblad, 1998).

For the purposes of this analysis, interventions were grouped into categories based in part on statistical considerations (such as the number of trials of a given intervention) and in part on clinical considerations (such as the way interventions are combined in clinical use; e.g., cognitive-behavioral therapy usually includes relaxation training). All relaxation techniques were grouped together on the basis of a trial comparing the use of PMR and autogenic training, which found that the type of training used made no significant difference in headache index (Janssen and Neutgens, 1986). The resulting categories for the meta-analysis were: control (wait-list), placebo (including sham biofeedback), relaxation (including PMR and autogenic training), thermal biofeedback, thermal biofeedback plus relaxation, EMG biofeedback, cognitive-behavioral therapy, and thermal biofeedback plus cognitive-behavioral therapy.

Analysis of Percentage Improvement Scores: Behavioral Trials

Because not all trials reporting continuous data permitted effect size calculation, the sample of studies included in the meta-analysis may be subject to selection bias. To investigate this potential bias, we calculated another measure of effectiveness, the percentage of improvement from pre- to post-treatment. We calculated this measure for all behavioral studies that provided pre-treatment and on- or post-treatment estimates of mean headache index or frequency. Because large differences between the percentage improvement scores from studies *included in the meta-analysis* and those from studies *excluded from the meta-analysis* would suggest bias, we compared the mean percentage improvement scores (weighted for sample size) of the two groups. The results of this

analysis are reported in the section on behavioral treatments.

Pair-wise Comparisons: Behavioral Trials with Control Arm

The same re-scaled and standardized outcome measures used in the behavioral meta-analysis were also used to calculate effect sizes for all pair-wise comparisons of an active behavioral treatment versus a control treatment using techniques described by Hasselblad (1998). These effect sizes are reported in Evidence Table 2. They show the results of individual trials in the same framework and terms as were used in the meta-analysis and should help the reader interpret both the results of the meta-analysis and the contribution of individual trials to those results.

This type of pair-wise effect size is a unitless index that describes the distance between two group means in terms of the population's standard deviation. These effect sizes are relative, and may best be interpreted by referring to the group mean differences observed in the original measures of the study. Unlike the odds ratio, however, the effect size point estimate provides some information about the magnitude of the treatment difference. For general purposes, effect size point estimates can be interpreted by the following conventional frame of reference: 0.2 is small, 0.5 is medium and 0.8 or more is a large effect size (Cohen, 1988). An effect size may be interpreted as statistically significant if its 95% confidence interval excludes zero (null effect). The effect size can vary between negative infinity and infinity.

Pair-wise Comparisons: Physical Treatment Trials

Only one of the trials considered in the section on physical treatments permitted the calculation of an effect size (Wittchen, 1983). The trial included three treatment arms, viz., wait-list control, acupuncture, and cognitive-behavioral therapy. For this trial, we calculated effect sizes for the pair-wise comparisons of acupuncture versus wait-list and acupuncture versus cognitive-behavioral therapy. The method used was the same as described immediately above for active versus control comparisons in the behavioral treatment report.

Behavioral Treatments

Background

This section describes the evidence for the efficacy of behavioral treatments for migraine. These therapies include biofeedback (BF), relaxation training, cognitive-behavioral techniques, and hypnotherapy. Two forms of biofeedback are analyzed: thermal biofeedback for increasing skin temperature and EMG biofeedback for reducing muscle tension. These therapies were often combined with relaxation training or other behavioral interventions in the included trials. The trials also provided data on several relaxation training methods. The most common were progressive muscle relaxation, in which patients are trained to alternately tighten and loosen muscle groups to induce relaxation (Bernstein and Borkovec, 1973); the autogenic (AT) phrases method, in which subjects use self-instructions of warmth and heaviness to promote a state of deep relaxation (Schultz and Luthe, 1969); and meditation or passive relaxation, the use of a silently repeated word or sound (Benson, 1975) or guided imagery to promote mental calm and relaxation. The trials also covered various cognitive-behavioral therapies for training patients in stress-management techniques, self-coping skills, social skills, and other methods for anticipating and responding to situations that might trigger or aggravate migraine. Many trials combined these cognitive-behavioral treatments with relaxation skills training or other behavioral

interventions. Hypnotherapy is also represented in this section, as it has also been studied as a treatment for migraine.

Studies Identified

Overview

Searches of all sources retrieved 75 publications reporting on 70 separate controlled trials of behavioral therapies for the treatment of migraine.

Thirty-one publications were excluded from our analysis. Appendix C lists these publications and provides reasons for their exclusion. Trials were most often excluded because they reported on blood volume pulse (BVP) biofeedback (nine trials) or on thermal biofeedback for decreasing skin temperature (four trials). The BVP biofeedback technique was excluded because it is technically difficult and rarely used clinically. Thermal biofeedback for decreasing skin temperature was deemed an inappropriate method to analyze because it trains patients to change skin temperature in the direction opposite to that required for the hypothesized therapeutic effect. Six trials were excluded because they did not provide separate results for patients with migraine, and four were excluded for having fewer than five subjects in each treatment arm or in the entire trial (see Appendix C for citations).

Forty-four publications representing 39 trials were thus included in this report (see Appendix D). One publication reported on two separate trials (Mitchell and Mitchell, 1971). Five publications were follow-up studies (Blanchard, Appelbaum, Guarnieri, et al., 1988; Daly, Zimmerman, Donn, et al., 1985; Holroyd, Holm, Penzien, et al., 1989; Silver, Blanchard, Williamson, et al., 1979; Sorbi, Tellegen, and Du Long, 1989); one (Solbach, Sargent, and Coyne, 1984) was a substudy of menstrual migraine in a population studied in another trial included in the report (Sargent, Solbach, Coyne, et al., 1986). Results from these follow-up studies and subanalyses are briefly described in the entry for the corresponding main trial in Evidence Table 1 and do not receive separate treatment.

Results from 18 trials reporting continuous outcome measures were combined and analyzed in a meta-analysis, the results of which are described below.

Five trials compared behavioral interventions with drug treatments for migraine, and one trial compared a behavioral intervention with a physical treatment (acupuncture). These comparisons were not included in the meta-analysis and are discussed in a separate section below.

Study Design and Quality

Basic design. Thirty-six of the included trials were parallel-group in design; three used matched pairs (Holroyd, France, Cordingley, et al., 1995; Jurish, Blanchard, Andrasik, et al., 1983; Nicholson and Blanchard, 1993). In all parallel-group trials except three (Anderson, Basker, and Dalton, 1975; Ilacqua, 1994; Lacroix, Clarke, Bock, et al., 1983), patients in the active groups were treated for at least 4 weeks. In all of the matched-pair studies, at least 19 patients were treated for at least 5 weeks. All of the matched-pair trials used thermal biofeedback (either alone or in combination with other therapies).

Headache monitoring, parallel-group trials. In all parallel-group trials except three (Anderson, Basker, and Dalton, 1975; Ilacqua, 1994; Lacroix, Clarke, Bock, et al., 1983), patients themselves (in the active groups) monitored headaches daily during treatment. However, in one of the three trials, headaches were recorded monthly by a therapist after conducting patient interviews (Anderson, Basker, and Dalton, 1975). In another trial, information was gathered by therapists using questionnaires administered before and after treatment (Ilacqua, 1994). In the third trial, data were gathered by therapists through interviews

and telephone calls to patients before and after treatment (Lacroix, Clarke, Bock, et al., 1983). The same trial also used the shortest treatment period mentioned in the trials (2 weeks). In two trials, patients monitored headaches for as long as 1 year (Anderson, Basker, and Dalton, 1975; Andrasik, Blanchard, Neff, et al., 1984).

In all but two of the parallel-group trials (Machado and Gómez de Machado, 1985; Richardson and McGrath, 1989), patients in the wait-listed control groups monitored headaches for approximately the same length of time as did the active groups. In one study, patients in the control group only monitored headaches for two baseline treatment sessions (Machado and Gómez de Machado, 1985). In another, the control group monitored headaches before and after, but not during, the treatment period used by the active groups (Richardson and McGrath, 1989).

Headache monitoring, matched-pair trials. In all matched-pair trials, both active and control groups monitored headaches daily for at least 5 weeks during treatment (Holroyd, France, Cordingley, et al., 1995; Jurish, Blanchard, Andrasik, et al., 1983; Nicholson and Blanchard, 1993).

Baseline or pre-treatment periods. In 31 of the parallel-group trials, headache measures were recorded for at least 4 weeks pre-treatment. The pre-treatment period for one trial was 1 week (Machado and Gómez de Machado, 1985), and for five others, the pre-treatment period ranged from 2½ to "several" weeks long (Daly, Donn, Galliher, et al., 1983; Friedman and Taub, 1984; Janssen and Neutgens, 1986; McGrady, Wauquier, McNeil, et al., 1994; Reading, 1984). In four trials, patients were interviewed prior to treatment to obtain global assessments of the intensity of their previous headaches (Anderson, Basker, and Dalton, 1975; Ilacqua, 1994; Lacroix, Clarke, Bock, et al., 1983; Sovak, Kunzel, Sternbach, et al., 1981).

In all matched-pair trials, headache measures were recorded for at least 4 weeks pre-treatment. In one trial (Nicholson and Blanchard, 1993), patients were formed into dyads and randomly allocated to either a 4- or 12-week period of pre-treatment headache monitoring. The time period varied because investigators used multiple pre-treatment periods (2 or 4 weeks) across subjects in seven pairs.

Quality scores. Quality scores for the included trials ranged from 1 (six trials) to 3 (two trials). The average score was 1.9. Scores for these trials are relatively low because none was double-blinded. Single-blinding was attempted in five trials (Blanchard, Appelbaum, Radnitz, et al., 1990; Brown, 1984; McGrady, Wauquier, McNeil, et al., 1994; Mullinix, Norton, Hack, et al., 1978; Reading, 1984).

Patient Populations

In 13 of the included trials, patients were recruited from newspaper or media advertisements; in 16, patients were referred by physicians. Two trials included patients recruited from pain clinics (Sovak, Kunzel, Sternbach, et al., 1981; Wittchen, 1983); one included in-patients at a rehabilitation center who had major injuries in addition to migraine (Lacroix, Clarke, Bock, et al., 1983); and one included patients recruited from a clinic specializing in nonpharmacological headache therapies (Jurish, Blanchard, Andrasik, et al., 1983). One trial included only elderly patients, whose ages ranged from 61 to 75 (Nicholson and Blanchard, 1993).

Three trials excluded patients who had received recent nonpharmacological treatment for migraine. In one, patients were excluded for having received "preventive biofeedback therapies" (Lake, Rainey, and Papsdorf, 1979); in another, for having received nonmedical headache treatments within the previous year (Passchier, van der Helm-Hylkema, and Orlebeke, 1985); and, in a third trial, for

having received cognitive-behavioral treatment within the previous 5 years (Richardson and McGrath, 1989).

One trial explicitly cited the migraine diagnostic criteria of the International Headache Society (Holroyd, France, Cordingley, et al., 1995), and 11 trials cited the Ad Hoc criteria. Most of the remaining trials described a variety of other diagnostic criteria without citing an established standard.

There were no other unusual inclusion or exclusion criteria.

Six trials did not report the percentage of patients who were women (Anderson, Basker, and Dalton, 1975; Andrasik, Blanchard, Neff, et al., 1984; Andreychuk and Skriver, 1975; Mitchell and Mitchell, 1971, Study 2; Mullinix, Norton, Hack, et al., 1978; Penzien, Johnson, Carpenter, et al., 1990). Six studies did not report the average age of the study population (Anderson, Basker, and Dalton, 1975; Andrasik, Blanchard, Neff, et al., 1984; Ilacqua, 1994; Mullinix, Norton, Hack, et al., 1978; Penzien, Johnson, Carpenter, et al., 1990; Sovak, Kunzel, Sternbach, et al., 1981). Among the trials that did provide such information, the average age of patients ranged from 14 to 77, and the percentage of patients who were women ranged from 63% to 100%.

Evidence for Efficacy

Results of Meta-Analysis

Effect sizes relative to wait-list controls. As described in the methodological introduction to this report, the behavioral interventions considered in this section were grouped into eight categories for the purposes of the meta-analysis. These groupings were based partly on statistical considerations (such as the number of trials of a given intervention) and partly on clinical considerations (such as the way interventions are combined in clinical use; e.g., cognitive-behavioral therapy usually includes relaxation training). All relaxation techniques were considered together on the basis of a trial comparing the use of PMR and autogenic training, which found that the type of training used made no significant difference in headache index (Janssen and Neutgens, 1986). The resulting categories for the meta-analysis were: control (wait-list), placebo (including sham biofeedback), relaxation (RLX), thermal biofeedback (TBF), thermal biofeedback plus relaxation (TBF + RLX), EMG biofeedback (EMG BF), cognitive-behavioral therapy (CBT), and cognitive-behavioral therapy plus thermal biofeedback (CBT + TBF).

A comprehensive list of trials and treatment arms included in, and excluded from, the meta-analysis is provided in Appendix E. Eighteen trials that (a) included comparisons between at least two of the above eight categories of interventions, and (b) reported sufficient information to calculate effect size estimates, were included in the meta-analysis. Summary effect sizes for each category of intervention, estimated by the multiple linear regression model, are reported in Exhibit 2.

The meta-analysis calculates effect sizes for each class of therapy relative to the wait-list controls. The placebo conditions have an effect size of 0.16, indicating slightly greater effectiveness than control treatments, but this difference was not significant. Note that the "placebo" conditions include a variety of experimental conditions designed to improve the validity of the comparison by single- or double-blinding, or by providing a credible alternative therapy with no therapeutic value. Relaxation training, EMG biofeedback, and cognitive-behavioral therapy obtained statistically significant and moderately large effect sizes of 0.55, 0.77, and 0.54, respectively. Thermal biofeedback plus relaxation is estimated to have a more modest (0.40), but still

Exhibit 2. Summary effect sizes from the meta-analysis

Intervention	Effect size	95% confidence interval
Control (wait list)	0	-
Placebo	0.16	(-0.31 to 0.63)
RLX	0.55	(0.14 to 0.96)
TBF	0.38	(-0.18 to 0.94)
TBF + RLX	0.40	(0.01 to 0.79)
EMG BF	0.77	(0.24 to 1.3)
CBT	0.54	(0.13 to 0.94)
CBT + TBF	0.37	(-0.23 to 0.97)

statistically significant, effect size. The two remaining conditions utilizing thermal biofeedback alone or in combination with cognitive-behavioral therapy had more modest effect sizes of 0.38 and 0.37, respectively, both of which failed to reach statistical significance.

Although effect sizes are difficult to interpret by themselves, examples from the included studies may illustrate how effect sizes can be interpreted in relation to the types of outcome measures described in the original studies. Evidence Table 2 lists effect sizes for active treatment versus control (wait-list) or "placebo" interventions for individual studies permitting these calculations. The summary effect sizes for relaxation, EMG biofeedback, and cognitive-behavioral therapy may be interpreted by observing Gauthier, Lacroix, Côté, et al. (1985), for example, which has an effect size of 0.73. The control group in this trial showed a 14% reduction in mean headache frequency from 11.8 to 10.2, while the active treatment group reduced headache frequency from 13.6 to 5.5. The significance of a smaller effect size of 0.29 is illustrated by Wittchen (1983). In this study, cognitive-behavioral therapy patients reduced the mean frequency of disabling headaches from 2.4 to 1.7, a 29% improvement, compared to the wait-list control patients who improved from 3.5 to 3.0, a reduction of only 14%.

Percentage improvement scores with respect to meta-analysis. Effect size estimates could not be derived for a considerable number of the trials included in the literature review, and thus the sample of studies included in the meta-analysis may be subject to selection bias. To investigate this potential bias, we calculated separate percentage improvement scores for those trials included in the meta-analysis and those not included in the meta-analysis. These scores are compared in Exhibit 3.

In the case of thermal biofeedback combined with relaxation training, the mean weighted percentage improvement of studies contributing and not contributing to the meta-analysis were nearly identical. In the case of thermal biofeedback, however, the studies not included in the meta-analysis showed higher percentage improvement scores. A similar discrepancy was seen in the case of cognitive-behavioral therapy. This suggests that the current effect size estimates for these treatments may *underestimate* the effect size that would have resulted if all studies could have been included. Conversely, in the case of

Exhibit 3. Percentage improvement scores in trials included in, and excluded from, the meta-analysis (MA)

Intervention	No. of studies *In* MA	Mean weighted % improvement (range), studies *In* MA	No. of studies *not* in MA	Mean weighted % improvement (range), studies *not* in MA
RLX	5	41% (6.2%-78%)	5	22% (3.4% - 62%)
TBF	3	30% (13% - 60%)	2	49% (24% - 86%)
TBF + RLX	8	33% (21% - 52%)	2	32% (21% - 87%)
EMG BF	3	51% (36% - 58%)	2	23% (20% - 24%)
CBT	5	40% (29% - 51%)	2	71% (68% - 76%)
CBT + TBF	5	35% (22% - 46%)	0	-

relaxation training, the studies not included in the meta-analysis showed lower percentage improvement scores, suggesting that the effect size estimates for this treatment may *overestimate* the effect size that would have resulted if all studies could have been included. The same applies to EMG biofeedback. These latter two treatment categories (EMG biofeedback and relaxation training) had the highest effect size estimates.

These results suggest that the difference in efficacy between relaxation training and thermal biofeedback may not be as great as the meta-analysis suggests, and might be a consequence of the selection of studies.

We did not attempt any adjustment to the effect size estimates based on these findings. Because percentage improvement scores are uncontrolled, they are a less valid means of assessing efficacy than are effect sizes. The observed differences in percentage improvement between the studies contributing to the effect size estimates and those not contributing do not threaten the validity of the meta-analysis; they do serve to draw attention to another potential source of variation in meta-analysis, that is, selection bias engendered by data reporting requirements.

Comparisons with Pharmacological Treatments

Described below are six comparisons of pharmacological treatments with behavioral treatments, none of which were included in the meta-analysis. All of the trials discussed below had a quality score of 2 (randomized, not double-blinded, dropouts described).

Hypnosis vs. prochlorperazine. Anderson, Basker, and Dalton (1975) compared six sessions of hypnotherapy with 5 mg of prochlorperazine (Stemetil®) taken 4 times per day for 1 month, followed by 5 mg taken twice per day for 11 months. Twenty-three patients in the hypnotherapy group and 24 in the drug treatment group were treated for 1 year. Pre-treatment data were provided by patients' global assessments of headache frequency and intensity (4-point scale) for the 6 months prior to treatment. Treatment data were gathered by therapists during monthly interviews and telephone calls with patients; thus, efficacy results were not based on daily headache recordings by patients.

During the first 6 months of treatment, patients in the hypnotherapy group reduced headache frequency better than did the group taking Stemetil®, but not significantly so ($p = 0.06$). From pre-

treatment to 1 year, the hypnotherapy group showed significant reductions in headache frequency ($p < 0.005$), whereas the Stemetil® group showed no significant changes ($p < 0.30$). The hypnotherapy group also reduced headache frequency significantly more during the second 6-month treatment period than it had during the first 6-month treatment period ($p<0.01$).

Thermal BF + relaxation vs. thermal BF + relaxation + propranolol. Holroyd, France, Cordingley, et al. (1995) was a matched-pair study that compared thermal biofeedback + relaxation with thermal biofeedback + relaxation + propranolol. Six dropouts were replaced in the study. Patients receiving the behavioral therapies alone ($n = 14$) were treated in three sessions over 3 months. Patients receiving the drug treatment ($n = 13$) received the same behavioral treatment, as well as 60, 120, or 180 mg of propranolol daily, with the dose being increased from the lower to the higher doses as a patient's tolerance increased. Patients recorded headache intensity 4 times daily on an 11-point scale for 4 weeks during pre-treatment and for 3 months during treatment. The percentage change in headache index (a measure combining headache intensity, duration, and frequency) was assessed by a physician at the end of treatment.

Patients receiving the combination of behavioral and drug treatments decreased headache index significantly better than did patients receiving the behavioral treatment alone ($p < 0.05$). Both treatment groups reduced headache index from pre- to post-treatment. The improvement was statistically significant for the group receiving the drug therapy ($p < 0.05$), but not significant for the group receiving behavioral treatment alone ($p < 0.10$). At the end of treatment, 92% of patients (12/13) who received the combined treatment and 57% of patients (8/14) who received the behavioral treatment alone showed at least a 50% reduction in headache index. The difference between the two proportions was statistically significant ($p < 0.05$).

Thermal BF + relaxation vs. ergotamine + compliance training. Holroyd, Holm, Hursey, et al. (1988) compared a therapy combining ergotamine tartrate + compliance training with thermal biofeedback + relaxation training. Both groups were "home-based" and therefore received minimal treatment by physicians. Patients receiving the drug treatment ($n = 18$) and those receiving the behavioral therapy alone ($n = 19$) were all treated in approximately three sessions. Compliance problems were identified in 70% of patients randomized to ergotamine use. These problems were the focus of the compliance training intervention, which presumably improved the appropriate use of ergotamine during the evaluation period. Both groups recorded headache intensity 4 times daily on an 11-point scale for 4 weeks of pre-treatment and 8 weeks of treatment. Efficacy results were determined from changes in headache index, which was an average of weekly headache intensity ratings.

Both treatment groups improved significantly from pre- to post-treatment, although neither group was better than the other (no p-values given). Fifty-three percent (10/19) of patients treated with thermal biofeedback + relaxation and 61% (11/18) of patients treated with ergotamine + compliance training showed at least a 50% reduction in headache index from pre- to post-treatment. The ergotamine group, however, showed a greater improvement in the first month of treatment than did the thermal biofeedback group ($p < 0.05$).

Although ergotamine was used as an abortive to treat acute episodes of headache, the outcomes of this study were evaluated over months, using a headache

diary. Thus, the outcome assessment was consistent with a preventive approach.

Thermal BF + relaxation + cognitive behavioral therapy vs. long-acting propranolol. Penzien, Johnson, Carpenter, et al. (1990) compared propranolol (60 to 160 mg Inderal® LA [long-acting]) with training in thermal biofeedback + relaxation + cognitive-behavioral coping skills (home-based). The pre-treatment period for both groups was 4 weeks. Eleven patients received three sessions of the behavioral treatments over 6 weeks, and 11 patients received the drug treatment for two sessions over 6 weeks. Both groups recorded headache information daily. Efficacy results were derived from a headache index (not described).

Although both groups improved significantly from pre- to post-treatment (p-values not given), neither treatment was significantly better than the other at reducing headache index (mean reductions: behavioral, 42%; propranolol, 44%). Forty-six percent (5/11) and 55% (6/11) of patients in the behavioral and propranolol groups, respectively, achieved a >50% reduction in headache index from pre- to post-treatment. Thirty-six percent (4/11) and 18% (2/11), respectively, were moderately improved (achieved 25% to 50% reduction), and 18% (2/11) and 27% (3/11), respectively, were not improved (< 25% reduction).

Because the number of patients in each treatment group was small (n=11 in each), the trial was of inadequate power to assess the effects of propranolol. The treatment duration was also short and may not have provided an adequate trial.

Thermal BF + relaxation vs. propranolol + analgesics. Sovak, Kunzel, Sternbach, et al. (1981) compared propranolol + analgesics with thermal biofeedback + relaxation (AT phrases). Twenty patients received the drug therapy, for which the dosage and treatment regimen were not described. A pre-treatment period was not specified either. Twenty-eight patients were treated in 8 to 10 sessions over a period (not clearly specified) that was at least 6 weeks long. Both groups of patients were recruited from pain treatment centers, and all patients recorded daily headache incidence, intensity (scale not specified), and duration. These data were incorporated into a headache index from which efficacy results were obtained.

The authors did not report results for between-group comparisons of headache index. Changes in this measure from pre- to post-treatment for each group were reported only on figures from which it was difficult to determine precise results. However, 54% (15/28) and 45% (9/20) of patients in the behavioral and drug therapy groups, respectively, improved with treatment, although investigators did not report the cutoff percentage used to determine "improvement."

Drug and/or behavioral treatments vs. control. One trial (Mathew, 1981) included seven active treatments and a control group. Two of the active treatments were each drug therapies (propranolol or amitriptyline); one was a behavioral treatment (EMG + thermal biofeedback + relaxation); one therapy combined the two active drugs; and three others combined the biofeedback treatment described above with either or both of the drugs just described. The control group received no preventive therapy, but a regimen of ergotamine tartrate and analgesics for acute migraine attacks. A total of 340 patients had migraine-only and 375 had mixed migraine and tension-type headaches. Eighteen patients in the migraine group and 29 in the mixed headache group dropped out of the study because of "untoward side effects," most of which occurred in the control group. For 1 month (pre-treatment) and 6 months

(treatment), all groups monitored headache frequency and intensity daily (on scales not specified). Efficacy results were computed from a headache index measure, which was derived from headache frequency and intensity ratings.

Improvement was expressed as the percentage of change in headache index from before treatment to the average of the last 3 months of treatment. For the migraine-only patients, each active group improved significantly better than did the control group (no p-values given). The improvement percentages ranged from 35% to 74% for the active groups, compared with 20% for the control group. The biofeedback-alone treatment resulted in 35% improvement, which was significantly better than that of the control group (no p-value given). The propranolol-alone group improved by 62%, and the amitriptyline-alone group improved by 42%. The combination of propranolol + biofeedback yielded the best improvement (74%); amitriptyline + biofeedback showed a 73% improvement.

For the mixed headache patients, the most effective treatment was the combination of biofeedback with amitriptyline plus propranolol (76%). Amitriptyline alone was significantly better than propranolol alone (60% vs. 52%) ($p < 0.01$). A combination of propranolol and amitriptyline was superior to either of those drugs singly ($p < 0.01$). Biofeedback alone yielded a 48% improvement. When biofeedback was added to each of the drug therapies, the percentages of improvement increased in each group (from 52% to 62% for propranolol; from 60% to 66% for amitriptyline).

Comparisons with Physical Treatments

A single trial (Wittchen, 1983) compared a behavioral treatment, psychological therapy (n = 10), with a physical treatment, acupuncture (n = 10). The trial also included a wait-listed control group (n = 10). Patients in both active groups received 10 treatment sessions over 8 weeks. Those receiving psychological therapy were treated in groups of 3 to 5 patients for 10 90-minute sessions of relaxation and self-coping skills training. Patients were recruited from a medically-oriented pain clinic and had histories of severe, long-term migraines. All groups recorded headache frequency and intensity (5-point scale) daily, as well as "frequency of disabling headaches," which was the mean number of days per week with severe performance impairments.

Investigators did not report between-group results for changes in headache frequency and intensity from pre- to post-treatment. However, each active group reduced headache frequency and intensity significantly over that time period ($p < 0.05$, each treatment group, each variable), although the control group did not (p-value not given). Similar results were reported for pre- to post-treatment changes in the frequency of disabling headaches.

Conclusions

Behavioral treatments for migraine have a consistent body of research indicating efficacy. The effect size data suggest that relaxation training, thermal biofeedback combined with relaxation training, EMG biofeedback, and cognitive-behavioral therapy are all modestly effective in treating migraine when compared to wait-list control. Trials using thermal biofeedback alone yielded an effect size point estimate similar to these treatments, but the estimate was not statistically significant, perhaps because only three studies contributed data. Trials of thermal biofeedback combined with cognitive-behavioral therapy also yielded an effect size that failed to reach statistical significance, though the point estimate

was not higher than that for cognitive-behavioral therapy alone and fairly similar to those for other treatments involving thermal biofeedback.

There are no statistically significant differences among the summary effect sizes for the combined and single active treatments. The trend for the combined treatments to have lower effect sizes is the opposite of what we would have expected to see; however, the effect sizes are not large enough to be attributed to random variation. These results are inconclusive, as are those of the individual studies designed to test whether combined behavioral approaches are better than single modes.

A large number of studies could not be included in the meta-analysis because they did not report variance data, even though they met all other inclusion criteria. Comparison of percentage improvement scores from trials included in, and excluded from, the meta-analysis did not substantially change our interpretation of the effect-size data.

The efficacy of drug treatments for migraine is generally established on the basis of double-blind comparisons with matching placebo. By contrast, most of the trials reviewed in this report compared behavioral treatments with control (wait-list) conditions. Double-blinding is impossible for most behavioral interventions, and effective single-blinding is also difficult to achieve in most cases. The use of wait-list controls (rather than credible placebos) and the lack of blinding make the behavioral trials more prone to bias than traditionally-designed drug trials, and, one might suspect, more likely to find a spurious statistically significant result (Type I error). Our meta-analysis estimates the magnitude of this bias by estimating the effect size for a variety of "placebo" conditions. This effect size was not significantly different from control, and was less than half the size of the weakest effect observed among the behavioral interventions included in the meta-analysis. This bias is too small to explain the effects observed.

The results of the meta-analysis provide little guidance for choosing among the treatments considered. The summary effect size estimates for the various categories of behavioral therapy are statistically indistinguishable. It should be noted, however, that this does not necessarily imply that these treatments are clinically interchangeable. Trials that report and analyze group mean values (as did most of the trials reviewed in this section) may obscure between-patient differences in response. Because of individual differences in response to treatment, some patients may benefit from one treatment, but not another. Very little research has been done on possible predictors of response to the various behavioral therapies considered in this section.

Another issue inadequately addressed in the literature is whether using different types of behavioral therapy in combination yields incremental benefits. For example, relaxation training is the least intensive of the behavioral therapies and is often the first to be tried clinically. Four of the trials we reviewed were designed to test the incremental benefit of adding thermal biofeedback (Blanchard, Theobald, Williamson, et al. 1978; Daly, Donn, Galliher, et al., 1983; Machado and Gómez de Machado, 1985) or cognitive-behavioral therapy (Mitchell and Mitchell, 1971) to relaxation training. Two other trials examined the effect of adding cognitive-behavioral therapy to thermal biofeedback (Blanchard, Appelbaum, Nicholson, et al., 1990; Lake, Rainey, and Papsdorf, 1979). None of these studies found a statistically significant incremental benefit to the added component, but all of them were too small

to detect small, but clinically significant differences.

Behavioral treatments have been directly compared with drug treatments for migraine in only a few trials. The effective migraine preventive drug propranolol and a behavioral therapy combining relaxation, thermal biofeedback, and cognitive-behavioral therapy provided similar improvement in headache index in one trial (Penzien, Johnson, Carpenter, et al., 1990). Adding propranolol to thermal biofeedback plus relaxation improved headache index significantly in two trials (Holroyd, France, Cordingley, et al., 1995; Mathew, 1981). Similarly, adding biofeedback to propranolol or amitriptyline treatment suggested improved efficacy (Mathew, 1981). Ergotamine tartrate plus compliance training was not significantly better than thermal biofeedback plus relaxation training (Holroyd, Holm, Hursey, et al., 1988).

Beyond the basic question of the efficacy of behavioral treatments, a small number of studies (described in Evidence Table 1, but not in the text of this section) addressed the efficacy of different methods of delivering behavioral therapies, testing the importance of home practice, intensity of therapist contact, and booster training. The provision of thermal biofeedback equipment and special instructions for home practice resulted in significant improvement in headache index beyond clinic-based thermal biofeedback in one study (Gauthier, Côté, and French, 1994), but not in another (Blanchard, Nicholson, Radnitz, et al., 1991). Clinic-based versus home-based relaxation plus thermal biofeedback training showed no differences in headache index in two studies either immediately after training (Jurish, Blanchard, Andrasik, et al., 1983; Blanchard, Andrasik, Appelbaum, et al., 1985), or during follow-up of up to 2 years (Blanchard, Appelbaum, Guarnieri, et al., 1988). Similarly, cognitive therapy plus relaxation training delivered in a standard eight-session clinic-based approach was not significantly better than a two-session minimal-therapist-contact protocol (Richardson and McGrath, 1989). Finally, a comparison of booster treatments in thermal biofeedback or relaxation training among subjects who had successfully completed a course of treatment failed to show any benefit to the booster treatments (Andrasik, Blanchard, Neff, et al., 1984).

Physical Treatments

Background

This section reviews the evidence for the efficacy of physical treatments for migraine. The interventions considered are acupuncture; transcutaneous electrical nerve stimulation; cervical manipulation; occlusal adjustment; and hyperbaric oxygen. Acupuncture is a therapy in which fine needles are used to pierce the skin to relieve pain, induce anesthesia, and achieve therapeutic purposes (Ingelfinger, 1980). In traditional Chinese practice, the needles are manipulated by hand (twirled) and heat may be applied to the needles to enhance therapeutic effectiveness (Tollison and Kunkel, 1993). In modern practice, electrical stimulation is sometimes applied to the needles (Tollison and Kunkel, 1993). Researchers believe that stimulating with the needles allows pain-killing endorphins to be released into the patient's system, thereby relieving pain (Tollison and Kunkel, 1993). TENS is a treatment in which "focused electrical shocks" are applied to "areas of the body feeling pain" (Elkind, 1997). Cervical manipulation is a therapy in which short- or long-term, high-velocity thrusts are directed at one or more joints of the cervical spine (neck). Occlusal adjustment

refers to dental procedures (such as grinding teeth or using occlusal splints) used to improve a patient's "bite" (relationship of upper and lower teeth) and thereby relieve muscle tension in the jaws that might otherwise induce or exacerbate migraine pain. Hyperbaric oxygen is a therapy requiring a patient to be placed in a hyperbaric chamber to increase pressurization of the blood gases. Pressurized (hyperbaric) oxygen produces higher blood levels of oxygen than does oxygen at normal atmospheric pressure (Myers and Myers, 1995). The single trial of hyperbaric oxygen identified by the literature search is included in this section even though this treatment is not unambiguously "physical."

Physical therapy stimuli produced by different means—by needle, electrically, manually, and so on—vary in frequency and intensity. The precise mechanism of their action on migraine is uncertain, nor is it clear whether they all share the same underlying mechanism or act in different ways.

Studies Identified

Overview

The literature review identified 13 publications reporting on 12 separate controlled trials of physical treatments for migraine (Ceccherelli, Ambrosio, Avila, et al., 1987; Dowson, Lewith, and Machin, 1985; Forssell, Kirveskari, and Kangasniemi, 1985; Hesse, Møgelvang, and Simonsen, 1994; Lenhard and Waite, 1983; Loh, Nathan, Schott, et al., 1984; Myers and Myers, 1995; Parker, Pryor, and Tupling, 1980; Parker, Tupling, and Pryor, 1978; Sheftell, Rapoport, and Kudrow, 1989; Solomon and Guglielmo, 1985; Vincent, 1989; Wittchen, 1983).

Lenhard and Waite (1983) was excluded from our analysis because it was not a controlled trial of acupuncture, but rather a study of its possible mechanism in the treatment of migraine. Parker, Pryor, and Tupling (1980) reported the results of a 20-month follow-up of patients from the trial originally described in Parker, Tupling, and Pryor (1978). Results from the follow-up are not separately reported in this section, but rather are briefly described in the entry for the main trial in Evidence Table 3.

Thus, our analysis included 12 publications reporting on 11 separate trials. The trials reported on the efficacy of the following treatments:

a. Acupuncture (6 trials)
b. TENS (2 trials)
c. Cervical manipulation and mobilization (1 trial)
d. Occlusal adjustment (1 trial)
e. Hyperbaric oxygen (1 trial)

In two trials, patients were treated for a single acute episode of migraine (Myers and Myers, 1995; Solomon and Guglielmo, 1985); in the other nine included trials, physical treatments were used as preventive therapies.

Study Design and Quality

Ten of the 11 included trials were single-period, parallel-group in design. The sole exception (Loh, Nathan, Schott, et al., 1984) was designed as a cross-over trial, but in fact a large percentage of the patients who started the trial (40%) refused to cross over to the alternative therapy at the end of the first treatment period; we therefore analyzed the first period results as a parallel-group trial.

None of the included trials was double-blinded. Quality scores ranged from 2 (nine trials) to 3 (two trials); the average score was 2.2.

Patient Populations

Recruitment settings varied widely. In only one case were patients clearly recruited from a primary care setting (Dowson, Lewith, and Machin, 1985). In other cases, trial participants were recruited from neurology or specialty

headache clinics (Forssell, Kirveskari, and Kangasniemi, 1985; Solomon and Guglielmo, 1985), by referral from general practitioners or neurologists (Loh, Nathan, Schott, et al., 1984; Vincent, 1989; Wittchen, 1983), through media ads (Parker, Tupling, and Pryor, 1978), or through a combination of newspaper advertisements and physician referrals (Hesse, Møgelvang, and Simonsen, 1994). In two cases, the patient recruitment setting was not described (Ceccherelli, Ambrosio, Avila, et al., 1987; Myers and Myers, 1995).

One of the two trials in which patients were treated for an acute headache episode excluded patients who had taken acute medications in the previous 24 hours (Solomon and Guglielmo, 1985); the other stated that patients refrained from taking such medications "during the study" (Myers and Myers, 1995). In one of the remaining trials, the use of preventive medication was part of the treatment protocol (Sheftell, Rapoport, and Kudrow, 1989); in five, preventive, but not acute, medication was permitted (Forssell, Kirveskari, and Kangasniemi, 1985; Hesse, Møgelvang, and Simonsen, 1994; Loh, Nathan, Schott, et al., 1984; Vincent, 1989; Wittchen, 1983); and in two, both preventive and acute medications were permitted (Dowson, Lewith, and Machin, 1985; Parker, Tupling, and Pryor, 1978). One trial provided no information on this topic (Ceccherelli, Ambrosio, Avila, et al., 1987).

One trial (Ceccherelli, Ambrosio, Avila, et al., 1987) was restricted to patients with migraine without aura. Four included patients with migraine with or without aura and no patients with mixed migraine and tension-type headache (Hesse, Møgelvang, and Simonsen, 1994; Myers and Myers, 1995; Parker, Tupling, and Pryor, 1978; Vincent, 1989). The remaining six trials included patients with migraine and patients with mixed migraine and tension-type headache. Two of these reported separate efficacy results for the two types of headache (Forssell, Kirveskari, and Kangasniemi, 1985; Solomon and Guglielmo, 1985); the other four did not (Dowson, Lewith, and Machin, 1985; Loh, Nathan, Schott, et al., 1984; Sheftell, Rapoport, and Kudrow, 1989; Wittchen, 1983).

One trial cited the IHS diagnostic criteria (Hesse, Møgelvang, and Simonsen, 1994); two, the Ad Hoc criteria (Forssell, Kirveskari, and Kangasniemi, 1985; Wittchen, 1983). The remaining articles did not refer to any established diagnostic criteria.

There were no other unusual inclusion or exclusion criteria pertaining to headache characteristics.

Two studies did not report the percentage of patients who were women (Sheftell, Rapoport, and Kudrow, 1989; Solomon and Guglielmo, 1985); those same trials and one more (Myers and Myers, 1995) did not report the average age of the study population. Among those trials that did report such information, the average age of patients ranged from 30 to 45, and the percentage of patients who were women ranged from 61% to 90%.

Evidence for Efficacy

Acupuncture

Relative to no treatment (wait-list). One small trial (n=10 in each treatment arm) compared a group of patients receiving acupuncture with a wait-list control group (Wittchen, 1983). Investigators reported that headache frequency and intensity were both significantly reduced from pre- to post-treatment in the acupuncture group ($p<0.05$ for both outcomes); improvement was not significant in the wait-list group (no p-values reported). The only data we were able to analyze were those on pre- to post-treatment changes in the frequency of

disabling headaches. Patients in the acupuncture group reported a 53% decrease in the frequency of such headaches, compared to a 14% decrease in the wait-list group. Based on the continuous data summarized in Evidence Tables 3 and 4, we calculated an effect size for this outcome for the acupuncture vs. wait-list comparison. The effect size was 0.31 (-0.57 to 1.2), which is not statistically significant. The investigators did not report the results of any direct between-group comparisons.

Relative to placebo (sham physical) treatments. Three trials compared acupuncture with sham physical treatments, either sham acupuncture (Ceccherelli, Ambrosio, Avila, et al., 1987; Vincent, 1989) or sham TENS (Dowson, Lewith, and Machin, 1985). Both of the trials comparing true acupuncture with sham found that the genuine intervention was significantly better at reducing headache intensity. Ceccherelli, Ambrosio, Avila, et al. (1987) yielded an especially large odds ratio in favor of genuine acupuncture (12.9 [2.07 to 79.7]). There were, however, problems with this trial. It was reported only in abstract form, and many details of methods and results were not reported. In particular, it was not clear how the assessment of "remaining pain" at the end of the treatment period was related to the pain scores recorded daily by patients, nor was it clear how baseline pain scores were established (no baseline period was described). Vincent (1989) reported a 44% decrease in mean total weekly pain scores from pre-treatment to 6-week post-treatment follow-up among a group of patients receiving genuine acupuncture; the corresponding reduction among patients receiving sham acupuncture was 13% ($p<0.03$). We were unable to calculate an effect size for this outcome because no variance data were reported. Both of the trials comparing acupuncture with a sham version of the same treatment were small (n=30 in both cases).

Dowson, Lewith, and Machin (1985) compared acupuncture with sham TENS. They reported that there was no significant difference between the two treatments for headache frequency: 8/25 patients receiving acupuncture (32%), and 6/23 receiving the placebo treatment (26%) reported a reduction in headache frequency of 50% or more post-treatment (no p-value reported). We calculated an odds ratio of 1.33 (0.381 to 4.67) for this outcome, which confirms the investigators' finding.

Relative to behavioral treatments. A single trial, already described above (under "wait-list" comparisons), compared acupuncture with a behavioral treatment, in this case a form of cognitive-behavioral therapy (Wittchen, 1983). Investigators reported that headache frequency and intensity were both significantly reduced from pre- to post-treatment in both the acupuncture and psychological therapy treatment groups ($p<0.05$ for both outcomes and both groups). We were able to analyze only the data on pre- to post-treatment changes in the frequency of disabling headaches. Patients in the acupuncture group reported a 53% decrease in the frequency of such headaches, compared to a 29% decrease in the psychological therapy group. On the basis of the continuous data summarized in Evidence Tables 3 and 4, we calculated an effect size for this outcome for the acupuncture vs. psychological treatment comparison. The effect size was 0.02 (- 0.85 to 0.90), which is not statistically significant. The investigators did not report the results of any direct between-group comparisons. The trial was small, with only 10 patients in each treatment arm.

Relative to pharmacological treatments. Hesse, Møgelvang, and Simonsen (1994) compared acupuncture

(n=38) with the beta-blocker, metoprolol (n=39), in a trial employing a double-dummy design. We were not able to analyze any of the outcome data reported by investigators, because non-parametric statistical methods were used, and median, rather than mean, values were reported for the major outcomes. The investigators found that there was no significant difference between the two treatments for headache frequency ($p>0.20$) or duration ($p>0.10$). Metoprolol was significantly ($p<0.05$) better than acupuncture at reducing the median global rating of attacks, a measure that incorporated headache severity, duration, and associated symptoms. Adverse events were reported by 36% of patients receiving metoprolol and by 8% of patients receiving acupuncture.

Loh, Nathan, Schott, et al. (1984) compared acupuncture with a variety of drug treatments for migraine (see Evidence Table 3 for details). The results included data from seven patients (of a total of 48) with tension-type headache only. The only outcome data reported concerned the patients' assessment of the effects of treatment. We have included the trial even though it is not clear from the written report how the patients' assessment of the effect of treatment was related to the data recorded daily in their headache diary. At the end of the first 3-month treatment period, 6/23 patients receiving acupuncture (26%) were "greatly improved," compared to 3/25 of those receiving pharmacological treatment (12%). These data yielded an odds ratio of 2.58 (0.565 to 11.8), which is not statistically significant. Our analysis of the categorical data (non-dichotomized) describing patients' assessment of the effect of treatment also showed no significant difference between the two treatments. (Investigators did not report results of any statistical analysis.) No data were reported on adverse events.

Other Physical Treatments

The literature search identified two trials of TENS and one trial each involving cervical manipulation, occlusal adjustment, and hyperbaric oxygen. These studies provided very limited information about the efficacy of these treatments.

Transcutaneous electrical nerve stimulation. Two trials examined the use of TENS therapy for the treatment of migraine (Solomon and Guglielmo, 1985; Sheftell, Rapoport, and Kudrow, 1989). Treatment was administered with the same Pain Suppressor Unit™ in both trials, but in Sheftell, Rapoport, and Kudrow (1989), the therapy was more specifically described as cranial electrotherapy stimulation (CES). In Solomon and Guglielmo (1985), TENS was used as treatment for an acute attack of migraine; in Sheftell, Rapoport, and Kudrow (1989), as a preventive treatment.

Solomon and Guglielmo (1985) compared sham TENS, subliminal TENS, and perceived TENS for the treatment of a single acute headache episode. Treatment was applied for 15 minutes to patients who had presented at a headache clinic with an acute attack under way. Very limited results were reported for migraine and mixed headache patients. Four of seven patients treated with perceived TENS (57%) reported success (defined as a reduction in headache severity of ≥ 2 points on a 10-point scale), as did 7/20 (35%) treated with subliminal or sham TENS (separate results were not reported for these groups). We did not calculate an odds ratio for this outcome because the definition of clinical success that was used did not meet our $\geq 50\%$ improvement criterion. The investigators' analysis found that, when analyzed for each headache type, the number of patients reporting success with perceived TENS was not significantly greater than with subliminal TENS or placebo (no p-values reported).

Sheftell, Rapoport, and Kudrow (1989) compared sham CES with genuine CES. Patients in both treatment groups also took either a beta-blocker, amitriptyline, or placebo. The trial was reported only in abstract form, and limited results were reported only for the group receiving active CES. It was thus impossible to compare the effects of sham and genuine CES.

Cervical manipulation. Parker, Tupling, and Pryor (1978) compared (a) cervical mobilization (oscillation of joint within its normal range of movement), performed by a medical practitioner or physiotherapist (n=28); (b) cervical manipulation (movement of joint beyond its normal range of movement), performed by a medical practitioner or physiotherapist (n=27); and (c) cervical manipulation, performed by a chiropractor (n=30). Patients received up to 16 biweekly treatments during the 2-month treatment period. Mobilization was used as a control treatment.

Pre- and post-treatment mean scores for headache frequency, severity, duration, and headache-related disability were all reported and analyzed by the investigators. When the three treatment groups were considered together, there were significant improvements, post-treatment, in frequency, severity, and disability, but not in duration. When the two groups receiving cervical manipulation, considered together, were compared with the group receiving mobilization therapy, there were no significant differences in outcomes. Comparison of the group receiving chiropractic manipulation with the other two treatment groups, considered together, showed a significant difference in favor of chiropractic manipulation for pain intensity; otherwise there were no significant differences. Finally, separate comparison of chiropractic manipulation with the control treatment (mobilization) alone showed no significant differences between them.

We were unable to calculate effect sizes for any of the reported outcomes because no variance data (or p-values) were reported.

Occlusal adjustment. Forssell, Kirveskari, and Kangasniemi (1985) compared occlusal adjustment with a sham version of the same therapy among patients with a primary diagnosis of headache. The length of treatment varied from patient to patient (see Evidence Table 3 for details). Results were reported for 2 months after the start of treatment, and were reported separately for migraine and mixed migraine + tension-type headache patients.

Among migraine patients receiving genuine occlusal adjustment (n=18), headache frequency decreased by an average of 2.0 attacks/month in comparison to the baseline period; for those receiving the sham treatment (n=17), the average reduction was 1.0 attack/month. Mixed headache patients receiving the active treatment (n=10) reported a reduction of 4.4 attacks/month, and those receiving the placebo treatment (n=10) reported a reduction of 3.2 attacks/month. We were not able to calculate effect sizes for this outcome because no variance data (or p-values) were reported.

Overall, investigators concluded that, for patients with migraine only, occlusal adjustment was not superior to the sham treatment. Patients with mixed migraine + tension-type headache were reported to have responded more favorably. According to investigators, the effect of the active treatment was significantly better than that of the placebo treatment, and both frequency and intensity were reduced (no p-values reported).

Hyperbaric oxygen. A single small (n=20) trial examined the use of hyperbaric oxygen (100% oxygen at 2

atmospheres of pressure) as a treatment for acute migraine. Normobaric oxygen (1 atmosphere of pressure) was used as a control. Study participants were all suffering an acute attack of migraine of "severe," "very severe," or "most severe ever" intensity. They were treated for 40 minutes inside a hyperbaric chamber. Clinical success was defined as a reduction in headache intensity to "mild" or "none" after treatment. Nine out of 10 patients (90%) treated with hyperbaric oxygen achieved this result, compared with 1/10 (10%) patients treated with normobaric oxygen. The investigators' analysis found the difference between the two treatments to be statistically significant ($p<0.005$). We calculated an odds ratio of 75.4 (4.43 to 1283) for this outcome, which is statistically significant, but which has a very wide confidence interval due to the small sample size.

Conclusions

Methodological and Design Problems

Despite widespread interest in, and advocacy for, a variety of physical treatments for migraine, such treatments have been little studied in controlled trials. Those trials that have been performed suffer from several methodological and design problems. Chief among these are the following:

- None of the trials considered in this report was double-blinded. In most (if not all) cases, blinding the practitioner responsible for delivering a physical treatment is impossible. Effective single-blinding may also be difficult to achieve. In theory, the use of sham treatments (e.g., sham acupuncture or TENS) may strengthen the validity of clinical trials by blinding the patient to treatment condition. However, problems remain with this approach: in most cases, there is no agreement on the most appropriate sham technique; many trials using sham controls do not measure or report the success of maintaining the single-blind; and non-specific and unintended cues from the therapist, who cannot be blinded to treatment condition, may lead to unblinding and to expectations of benefit or lack thereof, which can influence outcomes.
- The power of several of the trials reviewed in this section is reduced because of the use of an active treatment of established efficacy as the only comparator treatment (e.g., metoprolol in Hesse, Møgelvang, and Simonsen, 1994). Such a design reduces the expected difference between the two treatments, thus limiting the statistical power of the study. This problem is especially serious when a trial is too small to demonstrate the clinical equivalence of the two treatments.
- Many of the therapies considered here are delivered by a variety of practitioners, with different qualifications and training, in a variety of practice settings. This makes it difficult to compare one clinical study with another, and to generalize about the effectiveness of any particular form of treatment in practice. It also makes it difficult to achieve consensus on what constitutes an adequate trial of a given therapy.
- A final problem complicates many of the preceding problems: most of the trials reviewed in this section were too small to have sufficient statistical power to demonstrate a clinically important difference or to demonstrate equivalence between the physical treatments of interest and comparator treatments.

Summary of Evidence for Various Physical Treatments

Among the six trials of acupuncture, study designs and results are mixed. The single study using a wait-list control (no intervention) failed to find a significant result. Two trials comparing acupuncture to sham acupuncture in a single-blind fashion found a statistically significant benefit to genuine acupuncture. One of these (Ceccherelli, Ambrosio, Avila, et al., 1987) reported highly positive results, but did not report on whether single-blinding had been successfully achieved; the trial also had other, more serious methodological problems. The other study comparing sham and genuine acupuncture (Vincent, 1989) did report on the success of blinding. This study found a more modest, but still significant difference in favor of the genuine treatment (44% vs. 14% improvement in pain severity). A single trial comparing acupuncture with sham TENS found no significant difference between the two interventions. None of the trials comparing acupuncture to active pharmacological or behavioral treatments found acupuncture to be clinically or statistically significantly better than the comparator. Furthermore, none of these trials was large enough to demonstrate the equivalence of the interventions being compared.

Two studies of TENS or CES for migraine provide little support for the effectiveness of this treatment. A recent meta-analytical review of cranial electrotherapy (Klawansky, Yeung, Berkey, et al., 1995) for a variety of conditions reviewed one of these trials (Solomon and Guglielmo, 1985) plus another study conducted among tension-type headache patients (Solomon, Elkind, Freitag, et al., 1989). While the reviewers concluded that CES was effective, their analysis has been criticized for ignoring potential differences in response between migraine and tension-type headache patients (McCrory and Hasselblad, 1997).

One trial compared three manual interventions: a control condition (cervical mobilization), cervical manipulation performed by a medical practitioner or physiotherapist, and cervical manipulation performed by a chiropractor. A single statistically significant finding arose from the twelve planned and four post-hoc statistical comparisons. By comparing chiropractic manipulation to the other two groups, the investigators found that one of the four outcome variables reached statistical significance. Comparisons of chiropractic manipulation versus control (mobilization) alone resulted in no significant differences on any outcome variable. This trial provides little support for the use of manipulation or mobilization in patients with migraine. A recent comprehensive review of manipulation and mobilization for a variety of indications (Coulter, Hurwitz, Adams, et al., 1995) reached similar conclusions regarding manipulation for migraine, but suggested that it may be effective for tension-type headache. The same review also provided information about the potential harms of manipulative treatment. Hurwitz, Aker, Adams, et al. (1996) provided information of a similar nature, but specifically targeted neck pain and headache. Investigators used data from case reports and total cervical manipulations estimated from a community-based study of chiropractic services (Shekelle and Brook, 1991) to estimate the incidence of complications resulting from manipulative treatments of the cervical spine. Their estimates suggested that cervical spinal manipulation has a very low risk of serious complications. There is little information on the risk associated with mobilization procedures, but this is also likely to be very low.

A single trial of occlusal adjustment among patients with migraine and mixed migraine and tension-type headaches found no significant effect among migraine patients and a modest, but statistically significant, effect among mixed headache patients.

One small pilot study of hyperbaric oxygen for the treatment of acute migraine suggests a large effect. However, even if further research were to verify these results, the rare availability and high cost of the equipment involved would limit the clinical application of this treatment.

Future Research

Further research is required into the efficacy of currently available physical and behavioral treatments if their use for migraine is to be optimized. The recommendations listed below may be made.

Conduct and Reporting of Trials

1. The diagnosis of migraine even when made according to specific criteria such as the IHS criteria for migraine with aura and migraine without aura encompasses a wide range of symptomatology. Researchers should be as precise as possible in describing any operational inclusion or exclusion criteria they employ in addition to headache diagnosis, such as headache frequency, severity, and chronicity. Furthermore, researchers should state whether patients with co-existing tension-type headache were excluded. In addition to describing the inclusion and exclusion criteria applied, researchers should describe the relevant characteristics among the population actually enrolled.
2. Comparisons using recruitment from well-described clinical populations such as primary care practices or managed care organizations should be performed to expand the generalizability of the results reviewed in this report.
3. Future studies should include extended periods of follow-up for patients receiving behavioral or physical treatments and control subjects to evaluate the long-term effectiveness of such treatments.
4. There was tremendous variety in the way patients respond to the treatments reviewed in this report. Individual trials may not be able to identify patient characteristics that may predict a positive response to one treatment or another, but if trials were to report individual patient data, meta-analysis of such trials might have sufficient power to do this. Better data on predictors of good response to behavioral and physical treatments may help to select patients most likely to benefit from these treatments.
5. Adoption of certain standards recommended by the International Headache Society would strengthen the validity and comparability of trials of physical and behavioral treatments (International Headache Society Committee on Clinical Trials in Migraine, 1991); these standards include:
   a. Use of a prospective baseline period of at least 1 month;
   b. Use of a treatment period of at least 3 months;
   c. Use of a daily headache diary;
   d. Use of frequency of attacks per 4 weeks as main efficacy parameter rather than headache index or other measures; and
   e. Use of a 50% reduction in attack frequency compared with baseline as the criteria for individual response.

Future Research Directions

Physical Treatments

6. Research needs to be conducted to fill important gaps in the literature on physical treatments for migraine. None of the physical treatments has a sufficient body of evidence from which to draw firm conclusions about efficacy for migraine. Frequently-used physical treatments such as massage or mobilization therapy have not been tested at all against appropriate controls.
7. Sham acupuncture may result in opioid and other neuromediator changes in central nervous system and immune system cells, and may therefore be an inappropriate active control for studies of acupuncture. Although the Office of Alternative Medicine of the National Institutes of Health does not recommend use of double-blinding in studies of acupuncture, research on the effect of various sham acupuncture techniques should be performed to develop an empirical basis for selecting an acceptable control treatment.

   We note that NIH has recently targeted acupuncture as a priority for research funding. The NIH issued a program announcement in February 1998 to support pilot studies to establish the methodological feasibility of and to strengthen the scientific rationale for proceeding to full-scale, randomly controlled trials on the use of acupuncture to prevent, manage, or treat various symptoms/disorders. The emphasis of this program is on developing an appropriate study design rather than on attempting to complete insufficiently powered trials.

Behavioral Treatments

8. Further research needs to be conducted comparing behavioral and drug treatments for migraine and exploring possible combinations of these therapies. This type of research may have been hampered in the past by the fact that behavioral and drug therapies are usually provided, institutionally, by different professionals.
9. Research is also needed on acceptable control treatments for studies of behavioral treatments.
10. A number of behavioral treatments have provided evidence that they are effective. To help the largest number of patients possible, it would be beneficial to obtain more information about the optimal order or combination of those treatments.
11. More collaborative and multi-site studies of behavioral trials are needed. Much of the research on behavioral therapies has been performed at a relatively small number of centers by a few investigators and their trainees. The complex and subjective nature of much of the training leads to questions about whether the results observed with these interventions can be reproduced in other practice settings.

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Evidence Tables

*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Anderson, Basker, and Dalton, 1975	SPPG QS: 2 (r, ndb, dd)	N = 47 Age: N/S % female N/S Migraine; history ≥ 1 yr Chron: N/S Rec: N/S; England	***Prochlorperazine (Stemetil®):*** n = 24; taken as prophylactic in 5-mg doses 4 x /day for 1 mo, then 2 x /day for 11 mo; ergotamine to be taken at first warning of impending attack ***Hypnotherapy:*** n = 23; ≥ six sessions (length N/S) for 10-14 days; pts were treated with hypnotherapy & taught self-hypnosis skills; daily home practice of self-hypnosis	***HA frequency:*** No. of HAs/mo ***Frequency of incapacitating HAs:*** No. of patients experiencing Grade 4 HAs (on 4-point pain intensity scale) HA data recorded by therapist 1 x /mo throughout 1-yr treatment period; no daily HA diaries kept by pts. Initial 6-mo pretreat. data were obtained by pt's global assessment of HA frequency & intensity.	Patients in the hypnotherapy group reduced ***HA frequency*** better (not significantly) during the first 6-mo treatment period than did the group taking Stemetil® ($p = 0.06$). From pretreat. to 1 yr, the hypnotherapy group showed significant reductions in ***HA frequency*** ($p < 0.005$), whereas the Stemetil® group showed no significant changes ($p < 0.30$). The hypnotherapy group also reduced ***HA frequency*** significantly more during the second 6-mo treatment period than it had during the first 6-mo period ($p < 0.01$).	Dropouts: 0 Efficacy results not based on daily HA recordings; no. of HAs during treatment period recorded at once-a-month sessions with therapist; pretreat. data based on patient's global assessment of HA frequency & intensity

*Key to abbreviations follows; remaining footnotes are on last page of table.

Key: admin. = administrative; aft. = after; ANOVA = analysis of variance; AT = autogenic training; av. = average; bef. = before; beg. = beginning; beh. = behavioral; BF = biofeedback; BVP = blood volume pulse; chron = chronicity; cog. = cognitive; ctr. = center; db = double-blind; dd = dropouts described; diag. = diagnostic; dnd = dropouts not described; ea. = each; EEG = electroencephalogram; EMG = electromyograph; excl. = exclusion; f/up = follow-up; GP = general practitioner; grad. = graduate; HA = headache; HCl = hydrogen chloride; hist. = history; HM = headache monitoring; hr = hour; hypn. = hypnosis; IHS = International Headache Society; immed. = immediately; incl. = inclusion; LA = long-acting; M = migraine; max. = maximum; meds = medications; mg = milligram; mgmt. = management; mo = month; N = number of patients; ndb = not double-blinded; nonmed. = nonmedical; nonpharm. = nonpharmacological; nr = not randomized; N/S = not specified; pharm. = pharmacological; PMR = progressive muscle relaxation; posttreat. = posttreatment; pretreat. = pretreatment; pt = patient; public's = publications; QS = quality score; r = randomized; r+ = randomization described; rec = recruitment setting; rehab. = rehabilitation; relax. = relaxation; RET = Rational Emotive Therapy; s = seconds; SD = standard deviation; SE = standard error; SPPG = single-period parallel group; TBF = thermal BF; temp. = temperature; ther. = therapy; tot. = total; TTH = tension-type headache; t.v. = television; undergrad. = undergraduate; univ. = university; U.S. = United States; wk = week; WL = wait-listed; yr = year

*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Andrasik, Blanchard, Neff, et al., 1984	SPPG QS: 2 (r, ndb, dd)	N = 63 Age: N/S % female N/S Migraine (n = N/S) or migraine + TTH (n = N/S), as diagnosed by psychologist and neurologist Chron: N/S Rec: "Successfully treated" pts (PMR) & "successes & failures" (thermal BF) from previous study (Blanchard, Andrasik, and Neff, 1982); pts from that study recruited from stress disorders clinic in U.S.	***Regular contact ("minimal treatment" of thermal BF or relax.):*** n = 16; 10-15 min, 1 x /mo x 6 mo ***Booster treatment (more extensive treatment of thermal BF or relax.):*** n = 15; "full sessions" (length N/S), 1 x /mo x 6 mo; received additional training in "treatment benefiting them most" No treatment provided during months 7-12 Home practice: Daily (time N/S)	***HA index:*** Mean daily HA activity score per week (range: 0-20); composed of HA intensity, frequency, & other variables Both groups monitored HAs daily by diary for 4 wks (pretreat.) & 12 mo (treatment); a subjective assessment (by pt & by "significant other") of HA improvement was also obtained by questionnaire at end of months 3, 6, & 12.	Authors reported that neither treatment was significantly better than the other at reducing ***HA index*** (p-value not given). However, ***HA index*** improved in each group from pre- to posttreat. and from pretreat. to each of the 3, 6, & 12-mo f/up periods ($p < 0.01$, ea. group, ea. period). Eighty percent of pts (12/15) in the "booster" group and 69% of pts (11/16) in the "regular contact" group remained significantly improved at 1 yr (***HA index*** reduced ≥ 50% from pretreat.).	Dropouts: 32 (13/63 bef. treatment; also, 13/29 from "regular" & 6/21 from "booster" groups not included in final analyses) This trial excluded thermal BF & relax. pts who failed previous treatment.

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Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Andrey-chuk and Skriver, 1975	SPPG QS: 2 (r, ndb, dd)	N = 33 (See note) Age: N/S 85.7% female Migraine Chron: N/S Rec: Publi-city in local news media in U.S.	***Self-hypnosis:*** n = 10; 45 min 1 x /wk x 10 wks ***Thermal BF + relax. (AT phrases):*** n = 9; 45 min *total* session 1 x /wk x 10 wks (BF treatment in 15-min periods with short breaks between periods) ***BF for alpha enhancement:*** n = 11 (excluded) Home practice: Both groups 2 x /day (time N/S)	***HA index:*** Av. weekly rating; composed of HA duration & intensity HA intensity recorded hourly on 5-point scale Both groups monitored HAs daily by diary for 6 & 10 wks during pretreat. & treatment, respectively.	There were no significant differences between groups for reductions in ***HA index*** (p-value not significant). However, the thermal BF group showed a nonsignif-icant trend toward providing results better than those of the self-hypnosis group. Both groups showed significant reductions in ***HA index*** from pre- to "posttreat." (thermal BF, p = 0.01; self-hypnosis, p = 0.025). (Posttreat. data were calculated from the last 5 wks of the 10-wk treatment period.)	Dropouts: 3 We excluded one group (n = 11) treated with BF for "alpha enhancement."
Barrios, 1980	SPPG QS: 2 (r, ndb, dd)	N = 24 Age: 36.6 100% female Physician diagnosis of migraine; ≥ 1-2 HAs/wk for ≥ 2 yrs Chron: 16.9 Rec: Ads in univ. & city newspapers in U.S.	***Relax. (PMR):*** n = 8; pts treated in groups of five; *total* session: 45-60 min 2 x /wk x 4 wks ***Thermal BF + AT phrases:*** n = 7; pts treated in dyads; *treatment* session: 15 min BF + 15 min AT phrases 2 x /wk x 4 wks ***Social skills (beh. self-mgmt) training:*** n = 9; pts treated in groups of five; *total* session: 45-60 min 2 x /wk x 4 wks Home practice: All groups, 1/2 hr, 2 x /day (BF group with equipment)	***M frequency†:*** No. of migraine days/mo ***HA (all types) frequency:*** No. of HA days/mo ***HA intensity:*** Recorded on 4-point scale (time N/S) daily All groups monitored HAs daily by diary for 4, 4, and 4 wks during pretreat., treatment, and f/up, respectively.	No group was significantly better than any other at reducing any of the HA variables (p-values not given). All treatment groups combined reduced ***M frequency*** and ***HA intensity*** significantly from pre- to "posttreat." ($p < 0.01$ and $p < 0.001$, respectively).	Dropouts: 0 This study's 4-wk "f/up" period is analogous to the "posttreat." period typical of other studies.

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Methods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Bild and Adams, 1980	SPPG QS: 2 (r, ndb, dd)	N = 21 Age: 37.6 (range: 21-62) 70% female Migraine (Ad Hoc); ≥ 4 attacks/mo for ≥ 2 yrs; no prophylactic meds Chron: 22.1 Rec: Newspaper ad & physician referrals in U.S.	***WL (control):*** n = 6 ***EMG BF:*** n = 6; ten 30-min BF sessions, 2-3 sessions/wk; therapist N/S ***BVP BF:*** n = 7 (excluded) Home practice: N/S	***HA frequency†:*** No. of HAs/wk ***HA intensity:*** Measured daily (no. of times N/S) on 4-point scale ***HA duration:*** No. of hrs of HA activity per wk All groups monitored HAs daily by diary for 6, 4-5, & 6 wks for pretreat., treatment, & posttreat., respectively.	For reducing ***HA frequency***, the EMG BF treatment was not significantly better than the WL group (p-value not given). Although ***HA frequency*** declined in both groups, neither treatment showed a statistically significant reduction from pre- to posttreat. (p-values not given).	Dropouts: 2 A BVP group (n = 7) was excluded from our analysis.

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Study 1 Blanchard, Andrasik, Appel-baum, et al., 1985 **Study 2** Blanchard, Appel-baum, Guarnieri, et al., 1988 (Study 2 reports 1- and 2-yr f/up data on pts from Study 1.)	**Study 1** SPPG QS: 2 (r, ndb, dd)	**Study 1** ***M-only (Ad Hoc)*** N = 43 Age: 37.1 (range: 20-60) 71% female Chron: 18.8 Rec: N/S; U.S. ***Mixed M + TTH (Ad Hoc)*** N = 60 Age: 37.4 (range: 18-65) 77% female Chron: 17.4 Rec: N/S; U.S. **Study 2** 1 yr: N = 39 2 yrs: N = 33	**Study 1** ***Relax. (PMR) + thermal BF (clinic-based):*** n = 21 (M), 22 (mixed); 16 sessions (time N/S) over 8 wks, with thermal BF for last 10 sessions (tot. contact: 11.4 hrs) ***Relax. (PMR) + thermal BF (home-based):*** n = 18 (M), 26 (mixed); three clinic visits, approx. 1 x /4 wks, + two 10-15 min phone consultations between visits (tot. contact: 2.6 hrs) Home practice: Both groups, daily (time N/S), with tapes & equipment	**Study 1** ***HA Index:*** Av. daily HA score/wk (range: 0-20), composed of HA intensity & duration HA intensity recorded 4 x /day on 6-point scale Both groups monitored HAs daily by diary for 4, 8, 4 wks for pretreat., treatment, & posttreat., respectively; 1- and 2-yr f/ups were conducted.	**Study 1** Authors reported that for both HA groups (M-only and mixed M + TTH) neither treatment was significantly better than the other at reducing ***HA Index*** (no p-values given). However, each treatment showed a highly significant reduction in ***HA Index*** from pre- to posttreat. (M-only: clinic-based, $p < 0.001$; home-based, $p < 0.01$; mixed M + TTH: clinic-based, $p < 0.01$; home-based, $p < 0.001$). For M-only pts, 56% (10/18) of pts in the home-based group and 43% (9/21) in the clinic-based group improved (showed a ≥ 50% reduction in ***HA Index*** from pre- to posttreat.). For mixed M + TTH pts, 54% (14/26) in the home-based group and 55% (12/22) in the clinic-based group improved. **Study 2** Follow-up studies conducted after Study 1 ended showed that there were no significant differences in improvement between treatment groups at 1 or 2 yrs (no p-values given). However, there were significant improvements for both groups combined in ***HA Index*** from pretreat. to 1- and 2-yr f/ups ($p < 0.001$, both cases). There was also an overall improvement: 69% (27/39) of pts at 1 yr and 61% (20/33) of pts at 2 yrs had obtained a ≥ 50% reduction in ***HA Index.***	**Study 1** Dropouts: 4 (M-only); 12 (mixed M + TTH) **Study 2** Dropouts: 28 (1-yr f/up); 6 (2-yr f/up)

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dy	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
ıchard, ɔel- ım, holson, al., 90	SPPG QS: 2 (r, ndb, dd)	N = 97 Age: 40.3 (range: 21-67) 76.3% female Migraine (n = 45) or mixed migraine + TTH (n = 31) (both Ad Hoc); ≥ 1 M/mo for previous 4-6 mo Chron: 17.3 Rec: Media ads; physi-cian, friend, & self-referrals; U.S.	***WL (control):*** n = 17 ***Thermal BF + relax. (PMR) - "Home-based":*** n = 30; three sessions over 8 wks + two telephone contacts (av. 216 min/pt total contacts) ***Thermal BF + relax. + cog. ther. - "Home-based":*** n = 29; same design/schedule as for other BF group plus cog. ther. training (two additional office visits & additional phone calls - av. 330 min/pt total contacts) Both treatment groups of "minimal therapist-contact" design Home practice: Both BF groups daily (time N/S) - PMR for first 4 wks, hand-warming for second 4 wks of treatment	***HA Index†:*** Composed of HA intensity, duration, & frequency ratings. Calculated by adding 28 values from 1 wk and dividing by 7 to obtain average daily HA activity score (range 0 to 20) HA intensity measured 4 x /day on 6-point scale All groups monitored HAs daily by diary for 4, 8, & 4 wks for pretreat., treatment, & posttreat., respectively. Successfully treated pts & pts who refused additional treatment were followed up at 3 mo.	The thermal BF + relax. treatment was significantly more effective than WL (p = 0.011) at reducing ***HA index***, but it was not significantly better than thermal BF + relax. + cog. therapy (no p-value given). Authors reported that because of the small sample size the difference in improvement between the active groups did not appear to be clinically meaningful. Each BF group showed a significant reduction in ***HA index*** from pre- to posttreat. (p = 0.024 for the "without cog. ther." BF group; p = 0.008 for the "with cog. ther." BF group). The WL group showed no significant reduction in ***HA index*** over the same period (no p-value given).	Dropouts: 21

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Blanchard, Appel-baum, Radnitz, et al., 1990	SPPG QS: 2 (r, ndb, dd)	N = 148 Age: 38.6 (range: 21-61) 78.3% female Migraine (n = 74) (Ad Hoc); ≥ 1 HA/mo in last 6 mos & ≥1 HA in last mo; *or* mixed migraine + TTH (n = 42) (Ad Hoc); 3 TTH days/wk for past 6 mo & "some HAs" on ≥ 12 days in last mo Chron: 15.6 Rec: N/S; U.S.	***WL (control):*** n = 30 ***Pseudomeditation (placebo):*** n = 24; 35-40 min *total* sessions 2 x /wk x 8 wks; body awareness + mental control training – pts told "not to relax"; home practice: 20 min/day during treatment phase ***Thermal BF + relax. (PMR):*** n = 32; 30-35 min *treatment* sessions 2 x /wk x 8 wks (6 sessions PMR; 10 sessions TBF); home practice: 20-25 min/day with thermometer during treatment phase ***Thermal BF + relax. (PMR) + cog. ther.:*** n = 30; 30-35 min *treatment* sessions 2 x /wk x 8 wks (6 sessions PMR; 10 sessions TBF) + 15-30 min longer for some sessions + training in self-coping strategies; home practice: Same as thermal BF + relax.-only, plus cog. therapy "homework"	***HA Index†:*** Av. daily HA activity, obtained by summing 28 ratings of HA intensity, duration, & frequency from 1 wk & dividing by 7 HA intensity measured 4 x /day on 6-point scale All groups monitored HAs daily by diary 4, 8, & 4 wks pretreat., treatment, & posttreat., respectively. "Successfully treated" pts were followed up at 3, 6, & 12 mo.	The thermal BF groups combined reduced ***HA index*** from pre- to posttreat. significantly better than did the WL group ($p = 0.004$). The pseudomeditation group also improved compared to WL (p-value not given). There were no significant differences in efficacy among the three active groups. The three active groups each reduced ***HA index*** significantly from pre- to posttreat. (both thermal BF groups, $p < 0.001$, ea. case; pseudomeditation, $p < 0.05$). The WL group showed no significant reductions over this period (p-value not given).	Dropouts: 32

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Blanchard, Nicholson, Radnitz, et al., 1991	SPPG QS: 2 (r, ndb, dd)	N = 71 Age: 39.2 (range: 23-61) 78.0% female Migraine (n = 37) or mixed migraine + TTH (n = 22) (both Ad Hoc); no prophylactic meds Chron: 19.5 Rec: N/S; U.S.	***WL (control):*** n = 13 ***Thermal BF (+ AT phrases) with no home practice:*** n = 23; one 24-min (16-min w/ BF; 8 min without) session 2 x /wk x 6 wks ***Thermal BF (+ AT phrases) with home practice:*** n = 23; same treatment design/schedule as for thermal BF immed. above, except for addition of 20 min/day home practice with equipment	***HA index†:*** Weekly index calculated by summing 28 HA intensity ratings per wk & dividing by 7. Comprises HA intensity (rated 4 x /day on 6-point scale) & duration Active groups monitored HAs daily by diary 4, 6, & 4 wks during pretreat., treatment, & posttreat., respectively; the WL group did so for 4 wks during pretreat. & 8 wks during treatment.	Each thermal BF group reduced ***HA index*** significantly better than did the WL group ($p < 0.05$, each comparison). Neither BF group was significantly more effective than the other (p-value not given). Both active groups reduced ***HA index*** significantly from pre- to posttreat. (with home practice: $p = 0.007$, without home practice: $p = 0.034$). The WL group showed an *increase* in ***HA index*** from pre- to posttreat. at a level that was not statistically significant. Authors also reported that 52% (12/13), 48% (11/23), and 8% (1/8) of pts improved (i.e., achieved a ≥ 50% reduction in ***HA index*** score from pre- to posttreat.) in the thermal BF with home practice, thermal BF without home practice, and WL groups, respectively.	Dropouts: 12

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Study 1 Blanchard, Theobald, William-son, et al.,1978 **Study 2** Silver, Blanchard, William-son, et al., 1979 (Study 2 is a 1-yr f/up of pts from Study 1.)	**Study 1** SPPG QS: 2 (r, ndb, dd)	**Study 1** N = 37 Age: 38.7 (range: 21-77) 83.3% female Migraine; ≥ 2 attacks/mo Chron: N/S Rec: News-paper & t.v. ads; U.S. **Study 2** N = 18	**Study 1** ***WL (control):*** n = 10 ***Relax. (PMR) + home practice:*** n = 10; 30-min treatment 2 x /wk for 6 wks; home practice: 20-30 min/day ***Thermal BF + AT (relax.) + home practice:*** n = 10; 30-min treatment 2 x /wk for 6 wks; home practice: 5-10 min, 2-3 x /day **Study 2** ***Relax. (PMR) + home practice:*** n = 9 ***Thermal BF + AT (relax.) + home practice:*** n = 9	**Study 1** ***HA index†:*** Obtained by summing a pt's HA ratings ea. wk and dividing by 28 (HA rating is pain intensity recorded 4 x /day by pt on 6-point scale) ***HA frequency:*** No. of "discrete" HAs/wk (must have recorded "no pain" bef. & aft. ea. HA) Each of the above measures was derived from the last 2 wks of pretreat. (averaged) and the last 2 wks of treatment (averaged). ***Overall HA status:*** Rating of HA reduction in intensity & frequency on 4-category scale All groups monitored HAs daily by diary for 4, 6, & 12 wks for pretreat., treatment, & f/up, respectively.	**Study 1** Mean ***HA index*** and ***frequency*** scores were reported only on a graph (difficult to read data precisely). Authors reported that for ***HA index***, the active groups were each significantly more effective than the WL group ($p < 0.05$, both cases). There were no statistically significant differences between thermal BF & relax. (no p-value given). For reductions in ***HA index*** from pre- to posttreat., only the relax. group produced statistically significant results ($p < 0.001$). However, all three groups reduced ***HA frequency*** significantly over this period (BF & relax.: $p < 0.001$, both cases; WL, $p < 0.05$). **Study 2** There were no significant differences between the two treatment groups for reducing either ***HA index*** or ***frequency*** (p-values not given). Both groups reduced ***HA index*** and ***frequency*** significantly from pretreat. to 1-yr f/up ($p < 0.01$, each variable).	**Study 1** Dropouts: 7 4 pts had TTHs as well as attacks of migraine

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Brown, 1984	SPPG QS: 2 (r, ndb, dd)	N = 39 Age: 38 (range: 18-73) 89.7% female Migraine; ≥ 4 attacks/mo Chron: 90% ≥ 5 yrs Rec: Media ads; U.S.	***Subconscious reconditioning (placebo):*** n = 13; pts were shown relaxing scenes/slides ***Response group:*** n = 13; visualized relaxing scenes with accompanying responses (e.g., deep breathing, muscular relax.) ***Stimulus group:*** n = 13 (excluded) All groups treated during five 1-hr sessions for 4 wks. All tested bef. & aft. treatment to determine ability to control pain (with hands in cold water) Home practice: N/S	***HA index†:*** Defined as sum of intensity ratings for period (baseline, treatment, f/up) divided by no. of days in period. Intensity rated by pts every 2 hrs (scale not given) ***HA frequency:*** Sum of HAs during period, divided by no. of days in period ***HA intensity:*** Intensity ratings for period divided by no. of intensity ratings in period All groups monitored HAs daily by diary for 4, 4, & 8 wks for pretreat., treatment, & f/up, respectively.	The author included ***HA index & frequency*** in a composite of HA variables. The two active groups did not differ significantly from each other for percentage improvement of HA variables from pretreat. to treatment or from pretreat. to f/up ($p > 0.05$, both time periods). For percentage improvement of HA variables combined from pretreat. to treatment, the active groups combined showed significant improvement over the placebo group ($p < 0.01$). From pretreat. to f/up, the active groups combined again showed significantly greater improvement (for all HA variables) over the placebo group ($p < 0.05$).	Dropouts: 0 Note: We excluded from analysis a "stimulus group" treatment (n = 13) because it did not meet our inclusion criteria.

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Study 1 Daly, Donn, Galliher, et al., 1983 **Study 2** Daly, Zimmer-man, Donn, et al., 1985 (Study 2 is a 12-mo f/up of pts from Study 1.)	**Study 1** SPPG QS: 1 (nr, ndb, dd)	**Study 1** N = 34 Age: 38.2 80.4% female Classic or common migraine Chron: 19.0 Rec: Ads in univ. public's & locally; univ. health ctr. & physician referrals; U.S. **Study 2** N = 31	**Study 1** ***Relax. (PMR) (control) + AT phrases:*** n = 11 ***EMG BF + AT phrases:*** n = 10 ***Thermal BF + AT phrases:*** n = 10 All groups treated during nine ½-hr sessions over 5 wks Home practice: All pts asked to practice 2 x /day without equipment.	**Study 1** ***HA index†:*** Av. hourly HA intensity over life of HA (HA intensity ratings on 6-point scale gathered 4 x /day). ***HA frequency:*** No. of hrs/mo of HA All pts monitored HAs daily by diary for "several wks" (pretreat.), 5 wks, & 3 mo for pretreat., treatment, & f/up, respectively.	**Study 1** There were no significant differences among the three groups (p = 0.245) for reducing ***HA index***. No pairwise comparisons were reported. Ea. group reduced ***HA index*** significantly from pre- to posttreat. at 5 wks ($p < 0.05$, ea. case). **Study 2** There were no significant differences among the treatments at 12 mo for reductions in ***HA index*** (no p-values given). Authors stated that, on average, at 1 yr pts had maintained the reductions in ***HA index*** gained at 3 mo. in all three treatments.	**Study 1** Dropouts: 3 Low quality score (1).

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Methods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Friedman and Taub, 1984	SPPG QS: 2 (r, ndb, dd)	N = 76 (See note) Age: 38.4 (range: 18-55) 82.9% female Migraine (physician diagnosis); ≥ 2 attacks/ mo Chron: 17.2 (range: 1-44) Rec: Newspaper ads & physician referrals; U.S.	***WL (control):*** n = 10; one session, then HA monitoring only for 3 mo ***Relaxation:*** n = 8; home practice: 15-20 min/day ***Hypnosis (high susceptibility), with thermal imagery:*** n = 6 (excluded) ***Hypnosis (high susceptibility), without thermal imagery:*** n = 9 (excluded) ***Hypnosis (low susceptibility), with thermal imagery:*** n = 7 (excluded) ***Hypnosis (low susceptibility), without thermal imagery:*** n = 8 (excluded) ***Thermal BF + AT phrases:*** n = 7; home practice: 10-20 min/day The BF and relax. groups received five 1-wk sessions (three for treatment); all but WL received self-hypnosis training Home practice: BF & relax. groups, 2 x /day (BF: 10-20 min; relax.: 15-20 min) and at HA onset for 1 yr	***HA frequency:*** Calculated as "number of HA quarters per week" ***HA intensity:*** Defined as "highest HA intensity rating/wk" & derived from pain intensity scores recorded 4 x /day on 6-point scale Both active groups monitored HAs daily by diary for 3 wks pretreat. & 3 wks treatment, and throughout a 1-yr f/up; the WL group recorded HAs for 12 wks only.	Authors did not report between-group results for changes in ***HA frequency.*** ***HA frequency*** did not change significantly in the WL group from pretreat. to 3 mo (no p-value given). Authors did not report whether or not they analyzed results for the active groups separately over this period. However, from 6 to 12 mo, the active groups combined reduced ***HA frequency*** significantly ($p < 0.01$). (The WL group provided no data beyond 3 mo.)	Dropouts: 8 (from analyzed groups); 13 (from groups not analyzed) We excluded four hypnosis treatment groups (total n = 43) because allocation of subjects to sthose groups was based on hypnotic susceptibility testing, which might have confounded the treatment effect.

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Methods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Gauthier, Côté, and French, 1994	SPPG QS: 2 (r, ndb, dd)	N = 17 Age: 36.4 (range: 23-43) 100% female Migraine Chron: 20.7 (range: 4-40) Rec: From general population, method N/S; Canada	***Thermal BF without home practice:*** n = 9 ; two 20-min sessions/wk x 6 wks (in groups of four to five) ***Thermal BF with home practice:*** n = 8; two 20-min sessions/wk x 6 wks (in groups of four to five); home practice: One 20-min or two 10-min periods/day	***HA Index:*** Daily average level of HA activity. Obtained from diary of HA intensity measured on 6-point scale 4 x /day Both groups monitored HAs daily by diary for 5, 6, & 5 wks during pretreat., treatment, & posttreat., respectively.	For reducing ***HA index***, authors reported that the "home practice" thermal BF group was significantly better than the "no home practice" group ($p < 0.05$). The home practice group showed a significant reduction in ***HA index*** from pre- to posttreat. ($p < 0.05$), but the no home practice group did not (no p-value given).	Dropouts: 0
Gauthier, Lacroix, Côté, et al., 1985	SPPG QS: 3 (r+, ndb, dd)	N = 22 Age: 35.0 (range: 19-48) 100% female Migraine; ≥ 2 attacks/mo for ≥ 2 yrs; no prophylactic or abortive meds Chron: N/S Rec: General community ads in Canada	***WL (control):*** n = 7 ***Thermal BF:*** n = 8; two 20-60 min *treatment* sessions per wk x 6 wks (session duration determined by performance; interspersed with baseline recordings); one *test* session (tested 2 x /40 min; no BF) bef. & aft. treatment period ***BVP BF:*** n = 7 (excluded) Home practice: For BF groups, 20 min/day (once for 20 min or twice for 10 min)	***HA frequency†:*** Total no. of discrete HAs (HA preceded & followed by HA intensity rating of 0) ***HA intensity:*** Total of all intensity ratings (rated daily [time N/S] on 6-point scale) All groups monitored HAs daily by diary 5, 6, & 5 wks for pretreat., treatment, & posttreat., respectively.	There were no significant differences in efficacy between the two BF groups for reducing either ***HA index*** or ***frequency*** (p-values not given). However, both BF groups combined were significantly better at reducing ***HA intensity***, but not ***frequency***, from pre- to posttreat. than was the WL group ($p < 0.001$).	Dropouts: 0 We excluded from analysis a BVP BF group (n = 7). Post hoc power was small (≤ 0.20).

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Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Holroyd, France, Cording-ley, et al., 1995	Matched pairs QS: 2 (r, ndb, dd)	N = 33 Age: 31.7 (range: 16-52) 79% female Diagnosis of migraine (IHS) from 3 sources; ≥ 1 attack/mo; history ≥ 1 yr; no prophy-lactic meds for ≥ 6 mo bef. treatment Chron: 15.2 (range: 1-47) Rec: Univ. research clinic; U.S.	***Relax. + thermal BF:*** n = 14; two sessions (time N/S) 4 wks apart, followed by a third session + two telephone consultations (tot.: 12 wks) ***Relax. + thermal BF + propranolol Hcl:*** n = 13; same treatment design/schedule as for above therapy, plus 60, 120, or 180 mg of propranolol HCl daily (dose increased as tolerated); at 1 mo, max. tolerated dose was determined, then continued for 2 mo Home practice: Both groups, with tapes, manuals, & equipment (time N/S)	***HA Index:*** Av. daily HA activity, comprising HA intensity, duration, & frequency. Calculated as sum of four daily record-ings averaged over ea. wk (range: 0-40) HA intensity recorded 4 x /day on 11-point scale Both groups monitored HAs daily by diary for 4 & 12 wks for pretreat. & treatment, respectively; the percentage change in ***HA Index*** was assessed by physician at end of treatment.	Authors reported that pts who received relax.+ thermal BF + propranolol decreased ***HA Index*** significantly better than did pts who received relax. + thermal BF alone ($p < 0.05$). The relax. + thermal BF + propranolol group reduced ***HA Index*** significantly from pre- to posttreat. ($p < 0.05$); the relax. + thermal BF also reduced ***HA Index*** levels over this period, but not at a statistically significant level ($p < 0.10$). At posttreat., 92% of pts (12/13) who received the combined treatment and 57% of pts (8/14) who received relax. + thermal BF alone showed at least a 50% reduction in ***HA Index.*** There was a statistically significant difference between the two proportions ($p<0.05$).	Dropouts: 6 Dropouts were replaced in this matched-pair study.

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Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Study 1 Holroyd, Holm, Hursey, et al., 1988 **Study 2** Holroyd, Holm, Penzien, et al., 1989 (Study 2 was a 3-year f/up of the 21 pts success-fully treated [achieved ≥ 50% reduction in ***HA Index***] in Study 1.)	**Study 1** SPPG QS: 2 (r, ndb, dd)	**Study 1** N = 41 Age: 33 (range: 19-56) 65% female Migraine (n = 21) or mixed migraine + TTH (n = 20); ≥ 1 migraine attack/mo; recurrent HAs for ≥ 1 yr; no prophylactic meds ≥ 2 mo + no abortive meds ≥ 1 mo bef. treatment Chron: 14 (range: 2-37) Rec: HA pts at univ. re-search clinic; U.S. **Study 2** N = 21	**Study 1** ***Ergotamine tartrate + compliance training (home-based):*** n = 18; one clinic visit (time N/S) bef. & aft. month 1 & aft. month 2 of treatment + phone calls received aft. wks 2 & 6; meds given at first session & usage monitored aft. month 1; home practice N/S ***Thermal BF + relax. (home-based):*** n = 19; one clinic visit (time N/S) bef. & aft. month 1 & aft. month 2 of treatment + phone calls received aft. wks 2 & 6; home practice: Books & tapes (time N/S) **Study 2** ***Ergotamine + compliance training:*** n = 11 ***Thermal BF + relax.:*** n = 8	**Study 1** ***HA Index:*** Sum of four daily HA intensity ratings averaged over ea. wk (range: 0-40) (HA intensity rated 4 x /day on 11-point scale) HAs monitored daily by diary 4 x /day for 4, 8, & 4 wks for pretreat., treatment, & posttreat., respectively, & for a 3-wk f/up period 4 mo aft. last treatment. Three years later, authors followed up on the "successfully treated" pts. **Study 2** Data were obtained from 3-yr treatment histories (from 19 pts) + 1-mo HA diary (from 16 pts; 8 in ea. group).	**Study 1** Authors reported that both treatment groups reduced ***HA Index*** significantly from pre- to posttreat., but neither group was better than the other (no p-values given). Fifty-three percent (10/19) of pts treated with thermal BF + relax. and 61% (11/18) of pts treated with ergotamine + compliance training showed at least a 50% reduction in ***HA Index*** from pre- to posttreat. The ergotamine tartrate group, however, showed greater improvement in the first month of treatment than did the thermal BF group ($p < 0.05$). **Study 2** ***HA Index*** levels at posttreat. and at 3-yr f/up did not differ significantly between the two groups (no p-values reported). All pts had lower ***HA Index*** levels at posttreat. and 3-yr f/up than they had reported prior to treatment ($p < 0.01$, ea. period). At the 3-yr f/up, half of pts in each treatment group continued to show a ≥ 50% reduction in ***HA Index.*** Seventy-five percent of pts (6/8) in the thermal BF group continued to use thermal BF, whereas < 20% of pts (2/11) in the ergotamine tartrate group continued to use their treatment (although half were using some kind of medication). The difference between the two proportions was statistically significant ($p < 0.05$).	**Study 1** Dropouts: 4 **Study 2** Small sample size (19), and high dropout rate (22/41 original patients)

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Methods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Ilacqua, 1994	SPPG QS: 2 (r, ndb, dd)	N = 40 Age: N/S % female N/S Migraine Chron: N/S Rec: Volunteers at clinic in Canada	***WL (control):*** n = 10 (excluded) ***Combined (thermal BF + guided imagery):*** n = 10; six 20-min sessions ***Guided imagery:*** n = 9; six 20-min sessions ***Thermal BF + relax.:*** n = 9; six 20-min sessions No home practice	***HA frequency:*** Definition N/S HAs not monitored by diary. Questionnaires administered bef. & aft. treatment	The author reported that no group was significantly better at reducing ***HA frequency*** than any of the others, and there were no significant reductions in ***HA frequency*** from pre- to posttreat. in any of the treatment groups (no p-values given).	Dropouts: 2 A WL group (n = 10) was excluded because it was not a credible control (six 20-min sessions "just relaxing") HA data not recorded on daily basis
Janssen and Neutgens, 1986	SPPG QS: 2 (r, ndb, dd)	N = 33 Age: 33.4 63% female Classic or common migraine (n = 12) or migraine + TTH (n = 19), as diagnosed by two psychologists & two psychophysiologists Chron: 11.4 Rec: Referral by GPs in The Netherlands	***Relax. (AT phrases):*** n = N/S; 1 hr/wk x 12 wks ***Relax. (PMR):*** n = N/S; 1 hr/wk x 12 wks Pts treated in small groups (3-5 pts) Home practice: Both groups, 2 x /day (time N/S)	***HA index:*** Composed of HA intensity, frequency, & duration ratings ***HA frequency:*** Definition N/S ***HA intensity:*** Recorded every 4 hrs on 11-point scale Both groups monitored HAs daily by diary for 2-1/2, 12, & 2 wks for pretreat., treatment, & "posttreat.," respectively (prior to f/up 3 mo later).	From treatment (wks 12 & 13) to f/up (wks 25 & 26), there were no significant differences between the two groups for reducing ***HA index*** in M-only pts (p = 0.634) or in pts with mixed M + TTH (p = 0.052). The AT phrases treatment, however, showed a trend toward being more effective than the PMR treatment. Authors reported pre- and posttreat. results for ***HA index*** only on graphs from which it was difficult to determine precise data. Both groups reduced ***HA index*** from pretreat. to f/up (no p-values given).	Dropouts: 2 of total of 43 (not clear whether dropouts from M-only, M + TTH, or TTH-only groups) The trial also included a group of pts (n = 10) with TTH only; this group is not considered here.

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Jurish, Blanchard, Andrasik, et al., 1983	Matched pairs QS: 2 (r, ndb, dd)	N = 45 Age: 37.3 76% female Migraine (n = 20) or migraine + TTH (n = 20) (both Ad Hoc) Chron: 19.6 Rec: Clinic specializing in nonpharm HA treatment; U.S.	***Thermal BF + relax. (PMR) (clinic-based):*** n = 10 (M), 11 (M + TTH); sixteen 1-hr *total* sessions over 8 wks (BF training, ten 20-min sessions over 5 wks; relax. training, 12 sessions) (mean therapist time: 11.4 hrs) ***Thermal BF + relax. (PMR) (home-based, "minimal therapist-contact"):*** n = 10 (M), 9 (M + TTH); two 60-min & one 30-min clinic visits + two telephone consultations (mean therapist time: 2.6 hrs) Home practice: Both groups, 1 x /day with tapes, manuals, & equipment	***HA index:*** Av. daily HA activity score per wk (range: 0-20) HA intensity recorded 4 x /day on 6-point scale Both groups monitored HAs daily by diary for 4, 8, & 4 wks for pretreat., treatment, & posttreat., respectively.	Authors reported that an ANOVA analysis showed a nonsignificant difference between the two treatment groups for reducing ***HA index*** from pre- to posttreat. ($p = 0.09$). Each group achieved clinically meaningful improvements (i.e., showed a ≥ 50% reduction from pre- to posttreat.) in ***HA index***, with the minimal-contact group being significantly more effective ($p < 0.01$). Of the M-only pts, 70% (7/10 pts) in the minimal-contact group and 40% (4/10 pts) in the clinic-based group improved. Of the M + TTH pts, 89% (8/9 pts) in the minimal-contact group and 64% (7/11 pts) in the home-based group improved.	Dropouts: 5

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Methods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Kewman and Roberts, 1980	SPPG QS: 1 (nr, ndb, dd)	N = 40 Age: 40 (range: 21-75) 100% female Migraine; history ≥ 3 yrs; ≥ 72 HAs; ≥ 2 HAs/mo in last yr Chron: N/S Rec: Newspaper articles & physician referrals; U.S.	***WL (control):*** n = 11 (pts familiar with BF allocated to this group) ***Thermal BF (increase temp.):*** n = 11; 6-wk pretreat.; 9-wk-and-1-day treatment (10 sessions, approx. 7 days apart: three 10-min. periods of training/session); 6-wk posttreat.; undergrad. student; clinic; home practice: Amount N/S ***Thermal BF (decrease temp.):*** n = 12; same treatment schedule/design as for thermal BF "increase temp." above	***HA frequency†:*** No. of HAs/wk HAs were monitored daily by two types (N/S) of diaries for 6, 9, & 6 wks during pretreat., treatment, & posttreat., respectively.	Authors found no significant differences between the thermal BF (increase temp.) and WL groups for reducing ***HA frequency***. Neither group reduced ***HA frequency*** significantly from pre- to posttreat. (no p-values given).	Dropouts: 6 Pts were nonrandomly allocated to the WL group; moreover, we excluded the thermal BF "decrease temperature" group from our analysis; therefore, we designated this study as "nonrandomized" for the comparison between the thermal BF "increase temperature" and WL groups. Low quality score (1).

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Lacroix, Clarke, Bock, et al., 1983	SPPG QS: 1 (nr, ndb, dd)	N = 27 Age: 41.4 74.1% female Migraine Chron: 19.5 Rec: Physi-cian referral; 23/27 pts were in-patients at a rehab center and had major injuries in addition to migraine; Canada	***Relax. (PMR):*** n = 7; same treatment & test session design/schedule as for EMG BF except relax. tape used instead of BF during treatment; no tape used during test sessions ***EMG BF:*** n = 9; 15-min *treatment* sessions 9 x /wk x 2 wks with BF + *test* sessions without BF (to generalize learning) at beg. & end of ea. treatment session + two test sessions (20-25 min ea.) bef. & aft. treatment wk 1 and aft. treatment wk 2 ***Thermal BF:*** n = 8; same treatment & test session design/schedule as for EMG BF All patients treated in group sessions Home practice: Asked of all groups (time N/S), but equipment not provided	***HA frequency:*** Obtained by interviews ***Global subjective rating of improvement:*** Obtained by interviews; reported on 5-point scale Pretreat. & posttreat. are the time points bef. & aft. treatment, not week-long phases; f/up is at 6-8 wks & again at 6 mo. HAs not monitored by pt diaries. Data gathered by interviews & phone calls pre- & posttreat.	Results were reported only on graphs (difficult to read data precisely). There were no significant differences among the groups at posttreat., but all groups combined decreased ***HA frequency*** significantly from pre- to posttreat. ($p < 0.01$).	Dropouts: 3 Efficacy results not based on daily HA recordings. Low quality score (1).

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Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Lake, Rainey, and Papsdorf, 1979	SPPG QS: 2 (r, ndb, dd)	N = 24 Age: 33.0 (range: 20-56) 79.1% female Migraine; ≥ 3 severe HAs/ mo; no pre-ventive BF therapies Chron: 13.8 yrs (range: 6 mo - 37 yrs) Rec: News-paper ad & article; local physicians; U.S.	***WL (control):*** n = 6 ***EMG BF:*** n = 6; eight to ten 30-min sessions 2 x /wk x 4 wks + one 30-min session at 3-mo f/up ***Thermal BF + relax.:*** n = 6; same treatment schedule/design as for EMG BF, immed. above ***Thermal BF + cognitive (RET):*** n = 6; same treatment schedule/design as for EMG BF, above, plus three 30-40-min RET sessions with therapist Home practice: For three BF groups 10-20 min, 2 x /day	***HA Index†:*** Derived from HA intensity ratings ***HA Intensity:*** Recorded daily ea. hr on 6-point scale All groups monitored HAs daily by diary 4, 4, & 12 wks for pretreat., treatment, & f/up, respectively.	For ***HA index,*** "mean daily HA ratings" for each group were reported only on a graph (difficult to read data precisely). Analyses of the three active groups separately showed only EMG BF to be superior to WL ($p = 0.0076$). For reductions in ***HA index*** from pretreat. to 3-mo f/up, authors found BF (all three BF groups collapsed) to be superior to WL ($p = 0.048$).	Dropouts: 0
Machado and Gómez de Machado, 1985	SPPG QS: 2 (r, ndb, dd)	N = 19 Age: 33.8 (range: 14-56) 100% female Migraine; history ≥ 2 yrs; ≥ 2 HAs/wk; no prophylactic meds Chron: 12.3 Rec: Referral by physicians in Honduras	***WL (control):*** n = 7; pts received two baseline treatment sessions ***Relax. (modified PMR):*** n = 5; eight 25-min sessions 1 x /wk x 10 wks Relax. (modified PMR) + thermal BF: n = 7; eight 25-min sessions 1 x /wk x 10 wks Home practice: Both active groups, daily with tapes & as needed	***HA index:*** Composed of HA intensity & duration ***HA frequency:*** Defin-ition N/S All three groups monitored HAs daily by diary for 1 wk pretreat.; active groups also did so for ≈ 8 wks treatment; active groups were followed up 1 mo aft. treatment.	An ANOVA analysis showed that the two active groups were significantly better than the WL group for ***HA index*** ($p < 0.05$) and ***frequency*** ($p < 0.01$). There were no significant differences between the two active treatments for these outcomes (no p-values given). Both active groups reduced ***HA index*** and ***frequency*** significantly from pre- to posttreat., but the WL group did not (no p-values given; results reported on a figure from which it is difficult to obtain precise data).	Dropouts: 0 Unpublished manuscript

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Mathew, 1981	SPPG QS: 2 (r, ndb, dd)	***M-only*** N = 340 Age: 35.5 (av.) 93.5% female Chron: N/S Rec: N/S; U.S. ***Mixed M + TTH*** N = 375 Age: 40.2 (av.) 95.5% female Chron: N/S Rec: N/S; U.S.	***Control (abortive admin. of ergotamine + analgesic)***: n = 33 (M), 35 (mixed); total ergotamine intake ≤ 6 mg/wk ***Propranolol***: n = 38 (M), 38 (mixed); 20 mg 3 x /day initially; increased to 40 mg 3 or 4 x /day within first month of treatment, as tolerated ***Amitriptyline***: n = 32 (M), 31 (mixed); 25 mg/day for 2 wks, then increased to 50-75 mg/day in first month, as tolerated ***Biofeedback (combined EMG + thermal) + relax. (AT phrases)***: n = 31 (M), 31 (mixed); ten 1-hr sessions over 6 mo; home practice: ≤ 30 min, 1 x /day ***Propranolol + amitriptyline***: n = 38 (M), 36 (mixed); combined using dosages described above ***Propranolol + biofeedback (as above)***: n = 33 (M), 34 (mixed); combined using dosage and procedure described above ***Amitriptyline + biofeedback (as above)***: n = 38 (M), 39 (mixed); combined using dosage and procedure described above ***Propranolol + amitriptyline + biofeedback (as above)***: n = 30 (M), 37 (mixed); combined using dosages and procedure described above	***HA index***: Av. weekly index, derived from HA frequency & intensity ratings HA frequency: Definition N/S, but recorded daily HA intensity: Definition N/S, but recorded daily All groups monitored HAs by diary for 1 mo (pretreat.) and 6 mo (treatment).	Improvement was expressed as the percentage of change in ***HA index*** scores from pretreat. to the average of the last 3 mo of treatment. For the migraine-only pts, each active group improved significantly better than did the control group (no p-values given). The improvement percentages ranged from 35-74% for the active groups, compared with 20% for the control group. The biofeedback-alone treatment resulted in 35% improvement, which was significantly better than that of the control group (no p-value given). The combination of propranolol + biofeedback yielded the best improvement (74%); amitriptyline + biofeedback showed a 73% improvement. The propranolol-alone group improved by 62%, and the amitriptyline-alone group improved by 42%, with the former treatment being significantly better than the latter ($p < 0.01$). For the mixed HA pts, the most effective treatment was the combination of biofeedback with amitriptyline plus propranolol (76%). Amitriptyline alone was significantly better than propranolol alone (60% vs. 52%) ($p < 0.01$). A combination of propranolol and amitriptyline was superior to either of those drugs singly ($p < 0.01$). Biofeedback alone yielded a 48% improvement. When biofeedback was added to each of the drug therapies, the percentages of improvement increased in each group (from 52% to 62% for propranolol; from 60% to 66% for amitriptyline).	Dropouts: 67 (M), 94 (mixed) 18 (M) and 29 (mixed) pts dropped out because of "untoward side effects." Most adverse events occurred in the control group.

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McGrady, Wauquier, McNeil, et al., 1994	SPPG QS: 2 (r, ndb, dd)	N = 23 Age: 42 (range: 29-59) 87.0% female Migraine Chron: N/S Rec: Volun-teers	***Self-relax. (placebo):*** n = 12; two sessions (time N/S) over 8-12 wks ***Thermal BF + EMG BF + AT phrases (relax.):*** n = 11; 12 sessions (four EMG, eight thermal BF; time N/S) over 8-12 wks Home practice: Both groups, 10-15 min 2 x /day; BF group with relax. tape, self-relax. group without tape	***HA index†:*** Composed of HA frequency, intensity, & duration ratings & compiled as "average total pain score for pre- and posttest intervals" Both groups monitored HAs daily by diaries 15-24 days (pretreat.); 8-12 wks (treatment); & at end of treatment and 4-6 wks after treatment for 2 wks (posttreat.).	Authors reported that the BF group decreased ***HA index*** more than did the placebo group (no p-value given). Both groups together showed a trend toward significance for reducing ***HA index*** from pre- to posttreat. (p-value between 0.05 & 0.10). The BF group as a whole decreased pain scores by 35%; the placebo group *increased* pain scores by 7.7%. Six of 11 pts (55%) in the BF group and 3/12 pts (25%) in the WL group improved (i.e., decreased pain by ≥ 50% from pre- to posttreat.).	Dropouts: 0 We classified the active treatment as "thermal BF + relax." in our analysis because there were more BF than EMG sessions.

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Mitchell and Mitchell, 1971	**Study 1** SPPG QS: 2 (r, ndb, dd) **Study 2** SPPG QS: 1 (nr, ndb, dd)	**Study 1** N = 17 Age: 22.8 (range: 17-44) % female N/S Migraine Chron: 8 (range: 3-19) Rec: Volunteer univ. staff & students in Australia **Study 2** N = 20 Age: 27.9 (range: 18-55) % female N/S Migraine Chron: 9.2 (range: 2-18) Rec: Volunteer univ. staff, students, & others in Australia	**Study 1** ***WL (control):*** n = 3 (excluded) ***Relax. (PMR) application:*** n = 7; fifteen 50-60 min sessions (2 x /wk, with 2 days between sessions); first three sessions for PMR training, remaining sessions for application-of-skills training; home practice: Three 10-min periods/day ***Relax. + cog. ther. (combined desensitization):*** n = 7; fifteen 50-60 min sessions (2 x /wk, with 2 days between sessions); simultaneous training in applied relax., desensitization, & assertiveness therapy; home practice: N/S **Study 2** ***WL (control):*** n = 5; monitoring HAs only **Relax. + systematic desensitization:** n = 5; fifteen 50-60 min sessions ***Combined desensitization (previous pharm. therapy treatment):*** n = 5; same treatment design/schedule as for Study 1 ***Combined desensitization (no previous pharm. therapy treatment):*** n = 5; same treatment design/schedule as for Study 1	**Study 1** ***HA frequency:*** Number of HAs over 32 wks HA intensity recorded on 10-point scale at onset of ea. HA All groups monitored HAs at onset by diary for 8, 8, & 16 wks for pretreat., treatment, & f/up, respectively. Pts were interviewed after 8, 16, 24, & 32 wks. **Study 2** ***HA frequency:*** Same as for Study 1 Same HA monitoring design as for Study 1	**Study 1** There was a significant difference in reduction of ***HA frequency*** between the combined desensitization and the WL groups ($p < 0.01$), but no significant difference was found between the relax. application and the WL groups ($p = 0.47$). The combined desensitization treatment was significantly better than the relax. treatment ($p < 0.01$). Pts in the combined desensitization group showed a significant reduction in ***HA frequency*** from pretreat. to 32 wks (p-value not given), but there were no significant changes for the relax. application group during this period (no p-value given). Results were not provided for changes over time for the WL group. For reductions in ***HA frequency***, 100%, 71%, and 33% of pts in the combined desensitization, relax. application, and WL groups, respectively, improved from pretreat. to 32 wks. The threshhold for deciding improvement was not stated. **Study 2** The "combined desensitization (no previous pharm. therapy)" group reduced ***HA frequency*** from pretreat. to 32-wk f/up better than did any of the other three groups ($p < 0.05$, ea. comparison). Both combined desensitization groups together reduced ***HA frequency*** over time significantly better than did the systematic desensitization and the WL groups ($p < 0.001$). There were no significant differences between the two latter groups (no p-value given). Results for changes in ***HA frequency*** from pretreat. to f/up within ea. group were reported only on a figure from which it is difficult to determine precise data.	**Study 1** Dropouts: 0 WL group excluded because it had < 5 pts. One pt was nonrandomly allocated to control group because of unusually high number of HAs during pretreatment. **Study 2** Dropouts: 0 Five pts (with history of nonresponsiveness to pharm. therapy) were placed in combined desensitization (previous pharm. therapy) group. Both combined desensitization groups were excluded. Low quality score (1). score

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Mullinix, Norton, Hack, et al., 1978	SPPG QS: 2 (r, ndb, dd)	N = 12 Age: N/S (range: 16-58) 58.3% female Migraine; ≥ 2 attacks/mo Chron: N/S Rec: Referred by physicians due to frequent HAs or poor response to therapy; U.S.	***False thermal BF (placebo):*** n = 5; same treatment design/schedule as for thermal BF, except that BF signal was controlled by investigator to consistently indicate increasing temperature ***Thermal BF:*** n = 6; pts treated in six 30-min sessions over 2-3 wks + session at 1, 2, & 6 wks posttreat.; home practice: 2 x /day without equipment	***HA intensity†:*** Percentage improvement of average weekly HA intensity from pre- to posttreat. (HA intensity recorded hourly for 24 hrs on 3-point scale) HAs monitored by all pts hourly by diary for 24 hrs for ≥ 5 wks (mean 8.8 wks) during pretreat. (wks N/S), treatment (2-3 wks), & posttreat. (3 mo), respectively.	Authors reported that the two groups showed similar improvements: 33% (2/6) of pts in the thermal BF group and 20% (1/5) of pts in the false thermal BF group improved (i.e., ***HA intensity*** diminished ≥ 50% from pre- to posttreat.).	Dropouts: 1 Due to small sample size, the study lacked adequate power to detect differences between the two treatments.

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Nicholson and Blanchard, 1993	Matched pairs (7 pairs with multiple pretreat. periods [2 or 4 wks], across subjects) QS: 2 (r, ndb, dd)	N = 19 ***M-only (Ad Hoc)*** N = 4 Age: 68.8 (range: 63-75) 83% female Chron: 38.5 (range: 0-48) Rec: N/S; U.S. ***M + TTH (Ad Hoc)*** N = 6 Age: 64.7 (range: 61-69) 50% female Chron: 38.8 (range: 15-65) Rec: N/S; U.S.	***WL (control):*** n = 5 ***Relax. (PMR) + cog. ther. (either stress-coping or problem-solving) + thermal BF:*** n = 5; twelve 90-min sessions over 8 wks (2 x /wk for wks 1, 2, 5, & 6; 1 x /wk for other 4 wks); six sessions, PMR + cog. ther.; six sessions EMG BF (16 min) + cog. ther. Home practice: Relax. group, 2 x /day, with equipment	***HA index†:*** Sum of all 28 HA intensity ratings per pt ea. wk, divided by 7 (range: 0-20) HA intensity recorded 4 x /day on 6-point scale Both groups monitored HAs daily by diary for 4 or 12, 8, & 4 wks for pretreat., treatment, & posttreat., respectively.	Of five pairs, 3/5 pts receiving the active treatment improved (obtained a ≥ 50% reduction in ***HA index*** from pre- to posttreat.), while HA activity for the WL member of the pair remained unchanged. Of the same five pairs, 1/5 pts receiving the WL treatment improved while the member of the pair receiving the active treatment worsened. The authors did not report the statistical significance of these results.	Dropouts: 5 of total of 19 (not clear whether dropouts from M-only, M + TTH, or TTH-only groups) Dropouts were replaced in this matched-pair study. The trial also included a group of pts (n = 4) with TTH only; this group is not considered here. All pts "elderly" (age range: 61-75)

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Passchier, van der Helm-Hylkema, and Orlebeke, 1985	SPPG QS: 1 (nr, ndb, dd)	N = 59 Age: 36.5 (range: 17-56) 63% female Migraine (Ad Hoc); history ≥ 2 yrs; ≥ 2 HAs/mo or ≥ one long HA period/mo; no nonmed. HA treatment in last yr Chron: N/S Rec: News-paper ads in The Nether-lands	***WL (control):*** n = 11 ***Stress-coping + relax. (PMR):*** n = 11 ***Stress-coping + relax. (PMR) + thermal BF:*** n = 15 ***Stress-coping + relax. (PMR) + BVP BF:*** n = 14 (excluded) All active groups treated during twenty 45-min sessions (first 10 sessions, 2 x /wk; next 10, 1 x /wk) Home practice: N/S	***HA index:*** Calculated as product of HA frequency, intensity, & duration. ***HA frequency:*** Defin-ition N/S ***HA intensity***: Recorded 3 x /day on 5-point scale All groups monitored HAs daily by diary for 4, 15, & 4 wks for pretreat., treatment, & posttreat., respectively.	Authors reported that there were no significant differences among the treatments for reducing ***HA index*** or ***frequency*** (no means or p-values given). The authors measured ***HA index***, but did not report whether or not it changed significantly from pre- to posttreat. (no p-value given).	Dropouts: 8 A BVP BF group with 14 pts was excluded. Low quality score (1).
Penzien, Johnson, Carpenter, et al., 1990	SPPG QS: 2 (r, ndb, dd)	N = 22 Age: N/S % female N/S Migraine Chron: N/S Rec: N/S; U.S.	***Relax. + thermal BF + cog.-beh. coping skills (home-based):*** n = 11; three ses-sions (time N/S) x 6 wks + telephone consul-tations; therapist N/S; home practice (amt. N/S) ***Propranolol (60-160 mg Inderal® LA):*** n = 11; two sessions x 6 wks + telephone consultations	***HA index:*** Definition N/S Both groups monitored HAs daily by diary for 4, 6, & 4 wks for pretreat., treatment, & posttreat., respectively.	Authors reported that there were no significant differences between treatments for reductions in ***HA index*** (mean reductions: behavioral, 42%; propran-olol, 44%). Both groups reduced ***HA index*** significantly from pre- to posttreat. (p-values not given). Forty-six percent (5/11) and 55% (6/11) of pts in the behavioral and propranolol groups, respectively, were improved (achieved > 50% reduction in ***HA index*** from pre- to posttreat.). Thirty-six percent (4/11) and 18% (2/11), respectively, were moderately improved (achieved 25-50% reduction), and 18% (2/11) and 27% (3/11), respectively, were not improved (< 25% reduction).	Dropouts: 0 Abstract reporting prelimiinary results

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Reading, 1984	SPPG QS: 1 (nr, ndb, dd)	N = 28 Age: 45.6 100% female Migraine (diagnosed by physician) Chron: 23.4 Rec: Physi-cian referral; England	***False EMG BF (placebo):*** n = 7; mixture of false BF with "true" BF (max. of 3 s/min of true BF when pt exceeded a set threshhold) ***EMG BF (frontalis):*** n = 7 ***Thermal BF:*** n = 7 ***Skin conductance BF***: n = 7 (excluded) All groups: Ten 40-min *total* sessions over 5 wks (two 10-min BF periods per session) Home practice N/S	***HA frequency:*** Total no. of HAs/wk Pts recorded HA intensity as mild, moderate, or severe (scale N/S). All groups monitored HAs at onset daily by diary for 5, 5, & 5 wks during pretreat., treatment, & posttreat., respectively.	Authors reported that there were no significant differences in efficacy among the groups but that all groups improved significantly over time (no p-values given). For all treatment groups combined, there was a significant reduction in ***HA frequency*** from pre- to posttreat. ($p < 0.001$), in the number of severe HAs each wk ($p < 0.05$), and in the number of moderate HAs each wk ($p < 0.001$). There was no significant change in the number of mild HAs during this period. Authors did not report whether or not they analyzed results for the groups individually.	Dropouts: 0 The trial contained a skin conductance BF group with 7 pts that we excluded from our analysis. Low quality score (1).

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Richard-son and McGrath, 1989	SPPG QS: 2 (r, ndb, dd)	N = 51 Age: 35.6 (range: 23-48) 85.1% female Common migraine; ≥ 2 HAs/mo for ≥ 3 mos; no classical migraine symptoms; no prophy-lactic meds within last mo; no cog.-beh. ther. for HAs within 5 yrs Chron: 16.7 (range: 2-40) Rec: Media ads, nurses, & physicians in Canada	***WL (control):*** n = 17; HM daily for 4 wks pre- & posttreat., but none during 8 wks that others were receiving treatment ***Cog. ther. + relax. (PMR) - "Minimal therapist contact":*** n = 15; 1/2 hr bef. treatment & once during 5th wk of treatment ***Cog. ther. + relax. (PMR) - "Clinic-based":*** n = 15; 60 min 1 x /wk x 8 wks Home practice: For cog. ther. groups, daily practice with book + tapes	***HA index:*** Composed of HA frequency, duration, intensity, et al. (HA intensity rated 4 x /day on 6-point scale) ***HA frequency†:*** Defi-nition N/S All groups monitored HAs daily by diary for 4 wks during pretreat. & posttreat.; the cog. ther. groups also did so during the 8 treatment wks. Six months aft. treatment, all groups were asked to monitor HAs for 4 more wks.	For reductions in ***HA frequency*** from pre- to posttreat., there were significant differences between ea. of the active groups and the WL group (no p-values given), but none between the two active groups (no p-value given). The two active groups combined reduced ***HA frequency*** significantly over that period (no p-values given).	Dropouts: 4

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Study 1 Sargent, Solbach, Coyne, et al., 1986 **Study 2** Solbach, Sargent, and Coyne, 1984 (Study 2 was a study of a subset of pts from Study 1 with menstrual migraine.)	**Study 1** SPPG QS: 3 (r+, ndb, dd)	**Study 1** N = 193 Age: 35.7 83.8% female Classical or common migraine (Ad Hoc); ≥ 4 M days/mo for 6 mo/yr for 2 yrs; meds fail to relieve at least 1 severe M in past 2 yrs Chron: 17 Rec: Physi-cian referral, self-referral; U.S. **Study 2** N = 83 Age: 31 100% female As above, but only those attacks occurring 3 days bef. or aft. menstrual flow, or during flow, were considered Chron: 13	**Study 1** ***WL (control):*** n = 34; daily records; inactive during training ***Autogenic phrases:*** n = 34; daily records + AT phrases ***EMG BF:*** n = 34; daily records + AT phrases + EMG BF; six sessions with EMG BF, two without ***Thermal BF:*** n = 34; daily records + AT phrases + thermal BF; six sessions with thermal BF, two without Pretreat. (all groups): 2 x /4 wks (20 min sitting quietly); treatment: 5 min stabilization, then 15 min practice, 8 x /8 wks; f/up: 12 x /24 wks (no BF during f/up) Home practice: For three active groups, 15 min/day during treatment & f/up periods without equipment **Study 2** ***WL (control):*** n = 21 ***Autogenic phrases:*** n = 22 ***EMG BF:*** n = 24 ***Thermal BF:*** n = 16 Same treatment schedule/design as for Study 1	**Study 1** ***HA index:*** Included HA intensity, frequency, duration. Computed as daily 4-wk average of all HA variables ***HA frequency:*** Total days HA reported (≥ one HA/day counted as one HA) ***HA intensity:*** Reported on 100-point scale All groups monitored HAs daily by diary for 4, 8, & 24 wks during pretreat., treatment, & f/up, respectively. **Study 2** Same outcome variables as for Study 1, but only for Ms occurring 3 days bef. or aft. menstrual flow, or during flow	**Study 1** For reductions in ***HA frequency*** from pretreat. to f/up, there were no significant differences between thermal BF vs. AT phrases and EMG combined (p = 0.082) or between AT phrases vs. EMG BF (p-value not given). No other pairwise comparisons were reported. All four groups reduced ***HA frequency*** from pretreat. to f/up, with the three active groups combined being significantly better than WL (p = 0.016). Results were not reported for ea. separate group. **Study 2** Authors reported that there were no significant differences among the four groups for reductions in ***HA frequency***. However, all groups combined significantly reduced ***HA frequency*** from pretreat. to f/up (p < 0.001).	**Study 1:** Dropouts: 57 24 pts also had TTH, but TTH activity "minimal," and pts able to distinguish attacks of M from TTHs

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Sorbi and Tellegen, 1984	SPPG QS: 2 (r, ndb, dd)	N = 29 Age: 40.8 (range: 20-59) 76.2% female Migraine (n = 14) or migraine + TTH (n = 7) (both Ad Hoc); ≥ 2 attacks/ mo Chron: 16.9 (range: 6-35) Rec: Physi-cian referrals in The Nether-lands	***AT relax. + cog. ther. (stress-coping):*** n = 10; nine 50-min sessions x 5 wks (relax.) + nine 1-hr sessions weekly (cog. ther.) ***AT relax. + cog. ther. (stress-coping) + thermal BF:*** n = 11; same treatment design/schedule as above, except BF training incorporated into relax. portion (8/9 relax. sessions were for BF); BF portions: 40-min *total* (two 15-min *treatment* periods with two 5-min baseline periods per session) Home practice: Both groups, 2 x /day (time N/S)	***HA frequency†:*** Cal-culated by dividing the sum of discrete HAs by the number of days of a given time period. To be counted, a HA must have had a rating of zero bef. & aft. ea. HA. ***HA intensity:*** The sum of HA intensity values divided by the number of discrete HAs HA intensity recorded daily ea. hr on 5-point scale Both groups monitored HAs daily by diary for 4, 5 (relax.) or 8 (cog. ther.), and 4 wks for pretreat., treatment, and posttreat., respectively, and for a 7-mo f/up period.	Neither treatment group was significantly better than the other at reducing ***HA frequency*** ($p = 0.98$). Results were similar, whether pts received thermal BF treatment or not. However, both treatment groups significantly reduced ***HA frequency*** from pre- to posttreat. ("with thermal BF," $p < 0.05$; "without thermal BF," $p < 0.01$).	Dropouts: 8

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Study 1 Sorbi and Tellegen, 1986 **Study 2** Sorbi, Tellegen, and Du Long, 1989 (Study 2 is a 3-yr f/up of pts from Study 1.)	**Study 1** SPPG QS: 2 (r, ndb, dd)	**Study 1** N = 32 Age: 35.8 (range: 19-59) 82.8% female Migraine (Ad Hoc); ≥ 2 attacks/mo for ≥ 1 yr Chron: 17.3 (range: 1-52) Rec: GP & self-referrals; The Nether-lands **Study 2** N = 27	**Study 1** ***Relax. training (AT phrases):*** n = 13; 1 hr/wk x 9; relax. training first half of session, then application training; home practice: 2 x /day (time N/S) with tapes ***Cog. ther. (stress mgmt/self-coping training):*** n = 16; 1 hr/wk x 9; skills acquisition, rehearsal, application, & self-monitoring; home practice: As often as possible **Study 2** ***Relax. training (AT phrases):*** n = 10 ***Cog. ther. (stress mgmt/self-coping training):*** n = 14 No new treatment/training given to either group. Psychologists conducted 90-min f/up interviews.	**Study 1** ***M frequency***[t]: Sum of M attacks divided by number of days experienced. "Migraine attacks" defined as HAs with HA intensity rating ≥ 3, accompanied by nausea or vomiting & unilaterally located at least once. To be counted as an attack, HA had to be preceded & followed by one day without HAs. ***M intensity:*** Sum of HA intensity ratings for "migraine attacks" (defined above), averaged per attack, divided by number of attacks. HA intensity recorded 4 x /day on 5-point scale (HAs with rating of "1," the lowest rating, were excluded from analyses) ***Total HA frequency:*** Sum of all HAs (including those rated 1 or 2), divided by number of days Both groups monitored HAs daily by diary for 8, 8, & 8 wks for pretreat., treatment, & posttreat., respectively, and for 4 wks after posttreat. (then followed up ≈ 6-7 mo later). **Study 2** Same outcome measures & descriptions as for Study 1	**Study 1** Authors reported results for between-group comparisons only on a figure (difficult to read data precisely). They stated that "[t]he effects did not differ between the two types of training." For ***M frequency***, ***M intensity***, and ***total HA frequency***, both treatment groups showed significant reductions from pre- to posttreat. The relax. training group reduced ***M frequency*** by 40% ($p < 0.01$), and the cog. ther. group by 31% ($p < 0.05$). **Study 2** Authors reported that neither treatment group was significantly better than the other at reducing any of the HA variables from pretreat. to 3-yr f/up. However, at 3 yrs both groups had maintained the previously achieved reductions in ***M frequency*** (relax., 38%; cog. ther., 36%). The percentage of improvement from pretreat. to f/up was statistically significant in ea. case ($p < 0.05$, relax.; $p < 0.01$, cog. ther.).	**Study 1** Dropouts: 3 3 pts had TTHs in addition to Ms. **Study 2** Dropouts: 3 2 pts had TTHs in addition to Ms.

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Sovak, Kunzel, Sternbach, et al., 1981	SPPG QS: 2 (r, ndb, dd)	N = 58 Age: N/S (range: 30-57) 100% female Common or classical migraine; no HAs between attacks; severe, "vascular-type" pain; no meds for BF group Chron: N/S Rec: Pain treatment center; U.S.	***Drug therapy (propranolol + analgesics):*** n = 20; dosages and treatment regimen not described ***Thermal BF + relax. (AT phrases):*** n = 28; eight to ten 45-min sessions (2 x /wk for first 2 wks, then at intervals increasing until there were 4 wks between the last two sessions); home practice: 2 x/ day with equipment + 10-min tape	***HA index:*** Composed of HA incidence, intensity (scale N/S), & duration Both groups monitored HAs daily by diary during treatment (length of time N/S).	Authors did not report results for comparisons between the two treatment groups for ***HA index***. Changes from pre- to posttreat. for each group were reported only on figures from which it was difficult to determine precise results. Fifty-four percent (15/28) and 45% (9/20) of pts in the thermal BF and drug therapy groups, respectively, improved with treatment. Authors did not report the cutoff percentage used to determine "improvement."	Dropouts: 10

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*Evidence Table 1: Study Descriptions and Results: Behavioral Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Wittchen, 1983	SPPG QS: 2 (r, ndb, dd)	N = 30 Age: 39 (range: 24-53) 76.7% female Common or classical migraine (n = 21), mixed migraine + TTH (n = 7), or cluster (n = 2) (all Ad Hoc) Chron: 57% > 10 yrs Rec: Referral by GP or specialist; Germany	***WL (control):*** n = 10; HM only; recordings monitored by psychologist 1 x /mo x 4 mo ***Psychological therapy:*** n = 10; pts treated in groups of three to five; six 90-min sessions biweekly + four sessions 1 x /wk; treated in three phases (instruction, training, practice in relax. & self-coping skills) ***Acupuncture therapy:*** n = 10 (excluded) Home practice: N/S	***HA frequency:*** Mean number of HA days/mo ***HA intensity:*** Mean weekly intensity score; patients graded attacks on a scale of 1-5 (slight, moderate, relatively severe, severe, unbearable) ***Frequency of disabling HAs†:*** Mean number of days/wk with severe performance impairments HAs monitored daily by diary for 4, 8, & 4 wks during pretreat., treatment, & a 4-wk f/up, respectively; there was also an 8-wk f/up.	Authors did not report between-group results for changes in ***HA frequency*** and ***intensity*** from pretreat. to posttreat. However, ea. active group reduced ***HA frequency*** and ***intensity*** significantly from pre- to posttreat. ($p < 0.05$, ea. treatment group, ea. variable), but the WL group did not (p-value not given). Similar results were reported for pre- to post-treatment changes in the ***frequency of disabling HAs***.	Dropouts: 0 2 cluster HA pts included Pts referred for trial because of history of "severe long-term" M attacks. Acupuncture treatment group excluded from meta-analysis because there were no other trials comparing a behavioral treatment with acupuncture.

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**Quality score numbers: One point (for a total of five) is allocated for meeting (or subtracted for failing to meet) the following criteria: randomized (gains 1 pt if trial is described as such); randomized+ (gains 1 point if method of randomization is described); randomized- (loses 1 point if method of randomization is inadequate); double-blind (gains 1 point if trial is described as such); double-blind+ (gains 1 point if trial provides adequate description of double-blinding); double-blind- (loses 1 point if method of double-blinding is inadequate); dropouts described (gains 1 point if dropouts/withdrawals are described)

† Outcome measure analyzed in this report

*Evidence Table 2: Efficacy of Behavioral Treatments**

Study	Treatment Type	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size
			N	Before Treatment	After Treatment	% Improvement		
Anderson, Basker, and Dalton, 1975	Prochlorperazine (Stemetil®)	-	24	-	-	-	-	-
	Hypnotherapy	-	23	-	-	-	-	-
Andrasik, Blanchard, Neff, et al., 1984	Regular contact (thermal BF or relax. [PMR])	11/16 (69%)	16	-	-	-	-	-
	Booster treat. (thermal BF or relax. [PMR])	12/15 (80%)	15	-	-	-	-	-
Andreychuk and Skriver, 1975	Self-hypnosis	-	10	87.5	55.1	0.37	HI	-
	Thermal BF + relax. (AT phrases)	-	9	132.1	24.1	0.82	HI	-
Barrios, 1980	Relax. (PMR)	-	8	4.00	3.75	0.06	HF	†
	Thermal BF + AT phrases	-	7	6.57	4.00	0.39	HF	†
	Social skills (beh. mgmt)	-	9	6.89	3.56	0.48	HF	†
Bild and Adams, 1980	Control (WL)	-	6	2.40	2.00	0.17	HF	†
	EMG BF	-	6	2.20	1.40	0.36	HF	0.79 (0.08 to 1.49)
Blanchard, Andrasik, Appelbaum, et al., 1985 *(Migraine-only)*	Relax. (PMR) + thermal BF (clinic-based)	9/21 (43%)	21	2.29	1.42	0.38	HI	-
	Relax. (PMR) + thermal BF (home-based)	10/18 (56%)	18	2.26	1.21	0.46	HI	-

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*Evidence Table 2: Efficacy of Behavioral Treatments**

Study	Treatment Type	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size
			N	Before Treatment	After Treatment	% Improvement		
Blanchard, Andrasik, Appelbaum, et al., 1985 *(Mixed M + TTH)*	Relax. (PMR) + thermal BF (clinic-based)	12/22 (55%)	22	4.26	2.65	0.38	HI	-
	Relax. (PMR) + thermal BF (home-based)	14/26 (54%)	26	4.60	2.54	0.45	HI	-
Blanchard, Appelbaum, Nicholson, et al., 1990	Control (WL)	2/17 (12%)	17	2.48	2.31	0.07	HI	†
	Thermal BF + relax. (PMR) (home-based)	12/20 (40%)	30	3.02	2.34	0.23	HI	0.01 (-0.59 to 0.60)
	Thermal BF + relax. (PMR) + cog. ther. (home-based)	13/29 (45%)	29	3.21	2.31	0.28	HI	0 (-0.6 to 0.6)
Blanchard, Appelbaum, Radnitz, et al., 1990	Control (WL)	6/30 (20%)	30	2.51	2.53	-0.01	HI	†
	Placebo (pseudomeditation)	9/24 (38%)	24	3.07	1.94	0.37	HI	0.18 (-0.36 to 0.72)
	Thermal BF + relax. (PMR)	17/32 (53%)	32	3.53	2.05	0.42	HI	0.15 (-0.35 to 0.65)
	Thermal BF + relax. (PMR) + cog. ther.	15/30 (50%)	30	3.37	1.90	0.44	HI	0.19 (-0.31 to 0.70)

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Study	Treatment Type	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size
			N	Before Treatment	After Treatment	% Improvement		
Blanchard, Nicholson, Radnitz, et al., 1991	Control (WL)	1/13 (8%)	13	2.98	3.44	-0.15	HI	†
	Thermal BF + relax. (AT phrases) + no home practice)	11/23 (48%)	23	3.76	2.92	0.22	HI	0.12 (-0.56 to 0.80)
	Thermal BF + relax. (AT phrases) + home practice)	12/23 (52%)	23	3.91	2.65	0.32	HI	0.18 (-0.50 to 0.86)
Blanchard, Theobald, Williamson, et al., 1978	Control (WL)	-	10	0.85	0.66	0.22	HI	†
	Relax. (PMR) + home practice	6/11 †† (55%)	10 ††	0.98	0.17	0.83	HI	0.88 (-0.4 to 1.8)
	Thermal BF + relax. (AT phrases) + home practice	9/13 †† (69%)	10 ††	0.70	0.21	0.70	HI	0.80 (-0.11 to 1.7)
Brown, 1984	Placebo (subconscious reconditioning)	-	13	1.00	1.07	-0.07	HI	†
	Response group (relax.)	-	13	1.00	0.50	0.50	HI	1.06 (0.24 to 1.88)
Daly, Donn, Galliher, et al., 1983	Relax. ([PMR] + AT phrases)	6/11 (55%)	11	0.68	0.63	0.08	HI	†
	EMG BF + relax. (AT phrases)	7/10 (70%)	10	0.59	0.25	0.58	HI	†
	Thermal BF + relax. (AT phrases)	8/10 (80%)	10	0.76	0.37	0.51	HI	†

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*Evidence Table 2: Efficacy of Behavioral Treatments**

Study	Treatment Type	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size
			N	Before Treatment	After Treatment	% Improvement		
Friedman and Taub, 1984	Control (WL)	-	10	-	-	-	-	-
	Relax.	-	8	26.7	25.3	0.03	HF	-
	Thermal BF + relax. (AT phrases)	-	7	11.3	8.9	0.21	HF	-
Gauthier, Côté, and French, 1994	Thermal BF + no home practice	2/9 (22%)	9	2.67	2.73	-0.02	HI	-
	Thermal BF + home practice	5/8 (63%)	8	3.18	1.85	0.42	HI	-
Gauthier, Lacroix, Côté, et al., 1985	Control (WL)	N/S	7	11.8	10.2	0.14	HF	†
	Thermal BF	5/8 (63%)	8	13.6	5.5	0.60	HF	0.73 (-0.32 to 1.8)
Holroyd, France, Cordingley, et al., 1995	Relax. + thermal BF	-	14	5.21	2.63	0.50	HI	-
	Relax. + thermal BF + propranolol HCl	-	13	6.11	1.83	0.70	HI	-
Holroyd, Holm, Hursey, et al., 1988	Ergotamine tartrate + compliance training (home-based)	11/18 (61%)	18	7.55	4.81	0.36	HI	-
	Thermal BF + relax. (home-based)	10/19 (53%)	19	7.79	4.59	0.41	HI	-

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Study	Treatment Type	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size
			N	Before Treatment	After Treatment	% Improvement		
Ilacqua, 1994	Guided imagery	-	9	-	-	-	-	-
	Combined (thermal BF + guided imagery)	-	10	-	-	-	-	-
	Thermal BF + relax.	-	9	-	-	-	-	-
Janssen and Neutgens, 1986 *(Migraine-only)*	Relax. (AT phrases)	-	N/S	0.72	0.59	0.18	HI	-
	Relax. (PMR)	-	N/S	0.83	0.56	0.33	HI	-
Janssen and Neutgens, 1986 *(Mixed M + TTH)*	Relax. (AT phrases)	-	N/S	0.64	0.58	0.09	HI	-
	Relax. (PMR)	-	N/S	0.87	0.51	0.41	HI	-
Jurish, Blanchard, Andrasik, et al., 1983	Thermal BF + relax. (PMR) (clinic-based, both HA groups combined)	11/21 (52%)	21	3.45	2.13	0.38	HI	-
	Thermal BF + relax. (PMR) (home-based, minimal therapist-contact, both HA groups combined)	15/19 (79%)	19	3.59	1.47	0.59	HI	-
Kewman and Roberts, 1980	Control (WL)	-	11	1.23	1.0	0.19	HF	†
	Thermal BF (increase temp.)	-	11	0.98	0.85	0.13	HF	0.08 (-0.76 to 0.91)

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Study	Treatment Type	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size
			N	Before Treatment	After Treatment	% Improvement		
Lacroix, Clarke, Bock, et al., 1983	Relax. (PMR)		7	4.00	1.50	0.63	HF	
	EMG BF		9	2.50	2.00	0.20	HF	
	Thermal BF		8	4.00	0.55	0.86	HF	
Lake, Rainey, and Papsdorf, 1979	Control (WL)		6	1.00	1.17	-0.17	HI	
	EMG BF		6	1.00	0.48	0.52	HI	1.61 (0.31 to 2.91)
	Thermal BF + relax.		6	1.00	0.70	0.30	HI	1.09 (-0.12 to 2.30)
	Thermal BF + cog. ther. (RET)		6	1.00	0.79	0.21	HI	0.89 (-0.29 to 2.08)
Machado and Gómez de Machado, 1985	Control (WL)		7	8.80	10.6	-0.20	HF	
	Relax. (modified PMR)		5	2.60	1.20	0.54	HF	
	Relax. (modified PMR) + thermal BF		7	6.00	0.80	0.87	HF	
Mathew, 1981 *(Migraine-only)*	Control (abortive ergotamine)		33	3.40	2.72	0.20	HI	
	Propranolol		38	4.12	1.57	0.62	HI	
	Amitriptyline		32	3.93	2.28	0.42	HI	
	Biofeedback (thermal + EMG) + relax.		31	3.50	2.28	0.35	HI	
	Propranolol + amitriptyline		38	4.08	1.47	0.64	HI	

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*Evidence Table 2: Efficacy of Behavioral Treatments**

Study	Treatment Type	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size
			N	Before Treatment	After Treatment	% Improvement		
Mathew, 1981 *(Migraine-only)* continued	Propranolol + biofeedback	-	33	4.22	1.1	0.74	HI	-
	Amitriptyline + biofeedback	-	38	3.78	1.89	0.48	HI	-
	Propranolol + amitriptyline + biofeedback	-	30	4.31	1.17	0.73	HI	-
Mathew, 1981 *(Mixed M + TTH)*	Control (abortive ergotamine)	-	35	8.12	6.6	0.18	HI	-
	Propranolol	-	38	6.7	3.24	0.52	HI	-
	Amitriptyline	-	31	7.78	3.12	0.60	HI	-
	Biofeedback (thermal + EMG) + relax.	-	31	8.06	4.20	0.48	HI	-
	Propranolol + amitriptyline	-	36	7.36	2.51	0.69	HI	-
	Propranolol + biofeedback	-	34	6.32	2.41	0.62	HI	-
	Amitriptyline + biofeedback	-	39	7.10	2.42	0.66	HI	-
	Propranolol + amitriptyline + biofeedback	-	37	7.84	1.89	0.76	HI	-
McGrady, Wauquier, McNeil, et al., 1994	Placebo (self-relax.)	3/12 (25%)	12	1.19	1.24	-0.04	HI	†
	EMG BF + thermal BF + relax. (AT phrases)	6/11 (55%)	11	1.28	1.00	0.22	HI	0.11 (-0.71 to 0.93)

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*Evidence Table 2: Efficacy of Behavioral Treatments**

Study	Treatment Type	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size
			N	Before Treatment	After Treatment	% Improvement		
Mitchell and Mitchell, 1971 (Study 1)	Relax. (PMR) application	–	7	1.00	0.76	0.24	HF	–
	Relax. + cog. ther. (combined desensitization)	–	7	1.00	0.24	0.76	HF	–
Mitchell and Mitchell, 1971 (Study 2)	Control (WL)	–	5	1.00	0.93	0.07	HF	–
	Relax. + cog. ther. (systematic desensitization)	–	5	1.00	0.59	0.41	HF	–
Mullinix, Norton, Hack, et al., 1978	Placebo (false thermal BF)	1/5 (20%)	5	1.00	0.92	0.08	HI	†
	Thermal BF	2/6 (33%)	6	1.00	0.78	0.21	HI	0.25 (-0.94 to 1.44)
Nicholson and Blanchard, 1993	Control (WL)	–	5	1.00	0.90	0.10	HI	†
	Relax. (PMR) + cog. ther. (stress-coping or problem-solving) + thermal BF	–	5	1.00	0.54	0.46	HI	0.91 (-0.39 to 2.21)
Passchier, van der Helm-Hylkema, and Orlebeke, 1985	Control (WL)	–	11	–	–	–	–	–
	Cog. ther. (stress-coping) + relax. (PMR)	–	11	–	–	–	–	–
	Cog. ther. (stress-coping) + relax. (PMR) + thermal BF	–	15	–	–	–	–	–

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*Evidence Table 2: Efficacy of Behavioral Treatments**

Study	Treatment Type	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size
			N	Before Treatment	After Treatment	% Improvement		
Penzien, Johnson, Carpenter, et al., 1990	Propranolol	6/11 (55%)	11	-	-	-	-	-
	Relax. + thermal BF + cog. ther. (coping skills, home-based)	5/11 (46%)	11	-	-	-	-	-
Reading, 1984	Placebo (false EMG BF)	-	7	-	-	-	-	-
	EMG BF (frontalis)	-	7	-	-	-	-	-
	Thermal BF	-	7	-	-	-	-	-
Richardson and McGrath, 1989	Control (WL)	3/17 (18%)	17	15.53	15.20	0.02	HF	§
	Cog. ther. + relax. (PMR) - Minimal therapist contact	5/15 (33%)	15	14.5	10.5	0.28	HF	§
	Cog. ther. + relax. (PMR) - Clinic-based	7/15 (47%)	15	15.47	8.32	0.46	HF	§
Sargent, Solbach, Coyne, et al., 1986	Control (WL)	-	34	6.33	5.79	0.09	HF	-
	Relax. (AT phrases)	-	34	6.84	5.86	0.14	HF	-
	EMG BF	-	34	6.95	5.27	0.24	HF	-
	Thermal BF	-	34	6.99	5.51	0.21	HF	-

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*Evidence Table 2: Efficacy of Behavioral Treatments**

Study	Treatment Type	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size
			N	Before Treatment	After Treatment	% Improvement		
Sorbi and Tellegen, 1984	Relax. (AT phrases) + cog. ther. (stress-coping)	-	10	0.20	0.094	0.53	HF	†
	Relax. (AT phrases) + cog. ther. (stress-coping) + thermal BF	-	11	0.27	0.15	0.44	HF	†
Sorbi and Tellegen, 1986	Relax. (AT phrases)	-	13	0.19	0.11	0.40	HF	†
	Cog. ther. (stress mgmt)	-	16	0.12	0.08	0.31	HF	†
Sovak, Kunzel, Sternbach, et al., 1981	Drug therapy (propranolol + analgesics)	-	20	-	-	-	-	-
	Thermal BF + relax. (AT phrases)	-	28	-	-	-	-	-

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*Evidence Table 2: Efficacy of Behavioral Treatments**

Study	Treatment Type	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size
			N	Before Treatment	After Treatment	% Improvement		
Wittchen, 1983								
	Control (WL)	-	10	3.5	3.0	0.14	Freq. of disabling HAs	†
	Psychological ther.	-	10	2.4	1.7	0.29	Freq. of disabling HAs	0.29 (-0.59 to 1.17)
	Acupuncture ther.	-	10	3.4	1.6	0.53	Freq. of disabling HAs	§§

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**The "# Imprv'd/N (%)" and "N (Mean Value)" may occasionally differ because the efficacy data for each may have been derived at different times in the study (patients may have dropped out, thus reducing the number).

†Data from trial were included in meta-analysis, but this study does not provide an effect size for a comparison with a control group.

††Treatment numbers are from a later timepoint than those of "number improved"; numbers do not match because some patients dropped out.

§Trial was included in meta-analysis, but an effect size could not be calculated because data were stratified by headache severity.

§§Treatment was discussed in text but not included in the meta-analysis.

*Evidence Table 3: Study Descriptions and Results: Physical Treatments**

Study	Methods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Cecchelli, Ambrosio, Avila, et al., 1987	SPPG QS: 2 (r, ndb, dd)	N = 30 Age: 38 (range: 16-57) 70% female Common migraine Chron: N/S Rec: N/S; Italy	***Placebo = sham acupuncture***: n = 15 ***Acupuncture*** (using "well-known set of points"): n = 15 Both groups were treated once/wk for 10 wks—no further details provided	***Pain intensity:*** "Remaining pain" scored at end of therapy (10 wks); result described as "good" (remaining pain score between 0-50% of original score), "unsatisfactory" (remaining pain score 51-80% of original score), or "poor" (remaining pain score > 80% of original score)	***Pain intensity:*** 13/15 patients (87%) in the acupuncture group had a "good" result, 1/15 (7%) "unsatisfactory," and 1/15 (7%) "poor"; in the sham acupuncture group, the corresponding figures were 5/15 (33%), 4/15 (27%), and 6/15 (40%). Linear regression of the weekly sum of daily pain scores showed that genuine acupuncture significantly decreased pain intensity compared with initial pain scores ($p<0.001$), but that sham acupuncture did not (no p-value reported). "Weekly remaining pain" in the acupuncture group was 15.88% of initial pain; in the sham acupuncture group, it was 49.96% of initial pain. Authors stated that acupuncture was "significantly better" than sham acupuncture for this outcome, but did not report a p-value for this direct comparison.	Dropouts: 0 Abstract reporting few details of methods and results Not clear how the assessment of "remaining pain" related to daily pain scores recorded by patients Not clear how baseline/initial pain scores established

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*Evidence Table 3: Study Descriptions and Results: Physical Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Dowson, Lewith, and Machin, 1985	SPPG QS: 3 (r+, ndb, dd)	N = 48 Age: 40 (range: 14-68) 83% female Classical or common migraine; ≥ 2 HAs/wk; at least some patients also experienced "simple" HAs Chron: N/S Rec: Two primary care health centers in England	***Placebo = mock transcutaneous electrical nerve stimulation (TENS)*** (no current, but flashing red light): n = 23 ***Acupuncture*** (points selected depending on type and distribution of pain and patient's response; no electrical stimulation used): n = 25 4-wk baseline period, followed by 6-wk treatment period, followed by 24-wk follow-up period Acute and preventive med permitted	***Frequency:*** Number of patients with 50% reduction in frequency in first 4 wks post-treatment, compared with 4-wk baseline period ***Severity:*** Number of patients with 50% reduction in average pain intensity in first 4 wks post-treatment, compared with 4-wk baseline period; patients graded HA severity daily on scale of 0-6 (none, very mild, mild, not very severe, quite severe, very severe, almost unbearable)	There was no statistically significant difference between the two treatments for ***HA frequency:*** 8/25 patients (32%) in the acupuncture group experienced a reduction of 50% or more in HA frequency post-treatment, as did 6/23 patients (26%) receiving the placebo treatment (no p-value reported). Identical dichotomous results were reported for ***HA severity:*** 8/25 patients (32%) in the acupuncture group experienced a reduction of 50% or more in HA severity post-treatment, as did 6/23 patients (26%) receiving the placebo treatment (p = 0.65).	Dropouts: 9 patients (19%) failed to complete the 24- wk follow-up, but were included by investigators in the main efficacy analysis Investigators included data from both migrainous and "simple" HAs and reported that the two types of HA "appeared to respond in the same way to the treatments used"

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*Evidence Table 3: Study Descriptions and Results: Physical Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Forssell, Kirves-kari, and Kangas-niemi, 1985	SPPG QS: 3 (r+, db-, dd)	N = 96 Age: 30 (range: 17-52) 88% female Migraine (n = 36), muscle con-traction HA (n = 39), or combination HA (n = 21) (all Ad Hoc); most patients had symptoms of, and all had clinical signs of mandibular dysfunction Chron: N/S Rec: Neuro dept outpatient clinic in Finland	***Sham occlusal adjustment (superficial contact with nonfunctional surfaces; no splint therapy):*** overall n = 43; migraine n = 17; mixed HA n = 10 ***Occlusal adjustment (grinding plus splint therapy, if needed):*** overall n = 48; migraine n = 18; mixed HA n = 10 1-mo baseline period; period of treatment varied from patient to patient; mean *active* treatment and follow-up time (± SD) was 8.0 mos (± 2.9) (range: 5-20 mos); mean number of visits was 6.7 (± 2.3) (range: 4-14); duration of individual treatment session varied from 10 to 30 min; mean *sham* treatment and follow-up time was 3.9 mos (± 2.0) (range: 2-6); total number of visits was 3 in every case but one (mean 2.9 ± 0.2); minimum duration of treatment session was 20 min No prophylactic med allowed; symptomatic med OK	***HA frequency:*** (1) Number of patients with decreased frequency of HA post-treatment; (2) difference in mean HA frequency, pre- and post-treatment ***HA intensity:*** (1) Number of patients with decreased intensity of HA post-treatment; (2) difference in mean HA frequency, pre- and post-treatment; severity graded on scale of 1-5 (not described)	We did not consider the categorical data reported on the number of patients with decreased frequency or intensity of HA post-treatment because these data were not based on daily HA recordings, did not meet our ≥ 50% improvement criterion, and were not reported separately for non-TTH patients. Among migraine patients receiving active treatment, mean ***HA frequency*** decreased during the first two months of treatment by an average of 2.0 attacks/mo in comparison to the baseline period; among migraine patients in the sham treatment group, the average reduction was 1.0 attack/mo (no variance data reported; no p-value reported). Mixed HA patients receiving the active treatment reported a reduction of 4.4 attacks/mo; those receiving the placebo treatment, a reduction of 3.2 attacks/mo (no variance data reported; no p-value reported). Reductions in ***HA intensity*** were small in all groups (no data reported). Investigators concluded that, for patients with migraine only, occlusal adjustment was not superior to the sham treatment. Patients with mixed migraine + TTH responded more favorably. The effect of the active treatment was significantly better than that of the placebo treatment, and both frequency and intensity were reduced (no p-values reported).	Dropouts: 5 (5%), including 1 migraine patient and 1 mixed HA patient

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*Evidence Table 3: Study Descriptions and Results: Physical Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Hesse, Møgel-vang, and Simon-sen, 1994	SPPG QS: 2 (r, ndb, dd)	N = 85 Age: 45 (range: 25-70) 84% female Migraine w/ or w/o aura (IHS); history ≥ 2 yrs; 2-6 attacks/mo; able to distinguish migraine from TTH Chron: 23.4 yrs (range: 2-55) Rec: News-paper ads or referred by GP; Denmark	***Metoprolol + sham acupuncture*** (metoprolol 100 mg/day + superficial touching of myofascial trigger points in neck region with broad end of needle); n = 39 ***Placebo tablets + acupuncture*** (dry needling of myofascial trigger points in neck region; number of trigger points needled per treatment, interval between treatments, and total number of treatments determined individually by therapist): n = 38 4-wk baseline period, followed by 17-wk treatment period; no follow-up Non-trial preventive med and non-trial physical treatments not permitted; symptomatic med OK	***HA frequency*** (medians compared) ***Global rating of attack*** (scored for each HA on scale of 1-3: mild, moderate, severe; took into account severity, duration, and associated symptoms; medians compared) ***HA duration*** (medians compared)	Both treatment groups exhibited significant reductions in median ***HA frequency*** over the course of the trial ($p<0.01$). There was no significant difference between the two treatments ($p>0.20$). Metoprolol was significantly better than acupuncture for median ***global rating of attack*** ($p<0.05$). There was no significant difference between the two treatments for median ***HA duration*** ($p>0.10$). ***Adverse events (AEs):*** 14/39 patients (36%) taking metoprolol reported AEs on open questioning, compared to 3/38 (8%) receiving acupuncture.	Dropouts: 8 (9%) Non-parametric statistical analysis performed by investigators

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*Evidence Table 3: Study Descriptions and Results: Physical Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Loh, Nathan, Schott, et al., 1984	CrOv QS: 2 (r, ndb, dd)	N = 55 Age: 42 (range: 17-70) 69% female Migraine (n = 31), "muscle tension" HA (n = 7), or combination of both (n = 10) Chron: 19 yrs Rec: Referred by GPs to neurologist; England	***Medical treatment*** = prophylactic regimen using propranolol, clonidine, pizotifen, metaclopramide, Migraleve®, or Migril®: n = 25 as first treatment; n = 11 as second treatment ***Acupuncture*** (using classical Chinese points, ± electrical stimulation; minimum of 6 points needled per session): n = 23 as first treatment; n = 18 as second treatment No baseline period described; two 3-mo treatment periods; no follow-up Acute, but not preventive, med permitted during acupuncture treatment phase; acute physical treatments (ice, massage, etc.) OK	***Patients' assessment of treatment:*** appears to have been based on frequency, severity, duration, and other measures, though this is not certain; graded as "great improvement," "moderate benefit," "slight benefit," or "no benefit"	This was designed as a crossover trial, but 12/23 patients (52%) starting on acupuncture refused to change to medical treatment, and 7/25 (28%) starting on medical treatment refused to change to acupuncture. We therefore present results from the first period, considered as a parallel-group trial. ***Patients' assessment of treatment:*** At the end of the first treatment period, 6/23 patients (26%) treated with acupuncture reported "great improvement," 2/23 (9%) "moderate improvement," 3/23 (13%) "slight improvement," and 12/23 (52%) "no benefit." In the group receiving medical treatment, the corresponding figures were 3/25 (12%), 1/25 (4%), 2/25 (8%), and 19/25 (76%), No statistical analysis was described by the investigators. Our own analysis (χ^2) showed no significant difference between the two treatments.	Dropouts: 7 (13%); also, see immediately left on patients who refused to cross over to alternative treatment Not clear how patients' assessments of treatment were related to data recorded in their daily HA records 7/48 patients included in the efficacy analysis had TTH only

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*Evidence Table 3: Study Descriptions and Results: Physical Treatments**

Study	Methods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Myers and Myers, 1995	SPPG QS: 2 (r, ndb, dd)	N = 20 Age: N/S 70% female Migraine, diagnosed by a physician; current HA "severe," "very severe," or "most severe ever" Chron: N/S Rec: N/S; U.S.	***Normobaric oxygen (100% oxygen at 1 atmosphere of pressure):*** n = 10 ***Hyperbaric oxygen (100% oxygen at 2 atmospheres of pressure):*** n = 10 Patients treated for 40 min inside a hyperbaric chamber	***HA severity:*** Patients graded HA severity before entering and on exiting hyperbaric chamber on 10-cm descriptor scale, on which the six descriptors were "none," "mild," "moderate," "severe," "very severe," and "most severe ever"; investigators analyzed number of patients improving from one of the "severe" categories to "mild" or "none"	***HA severity:*** All patients reported "severe," "very severe," or "most severe ever" pain upon entering the hyperbaric chamber. After the 40-min treatment, 9/10 patients (90%) in the hyperbaric group reported "mild" pain or "none"; 1/10 patients (10%) in the normobaric group had this response. The difference between the two groups was statistically significant ($p<0.005$).	Dropouts: 0 No "untoward effects" of treatment were reported by patients Treatment modalities used to treat single acute episode of HA

*Key: AE = adverse event; Assoc = Association; CES = cranial electrotherapy stimulation; Chron = chronicity; cm = centimeter; CrOv = cross-over; db = double-blind; dd = dropouts described; dept = department; ES = effect size; GP = general practitioner; HA = headache; IHS = International Headache Society; MD = medical doctor; med = medication; mg = milligram; min = minute or minutes; mo = month; mos = months; N or n = number of patients; ndb = not double-blind; neuro = neurology; nr = not randomized; N/S = not specified; PT = physiotherapist; QS = quality score; r = randomized; Rec = recruitment setting; SD = standard deviation; SPPG = single-period, parallel-group; TENS = transcutaneous electrical nerve stimulation; TTH = tension-type headache; VAS = visual analog scale; wk = week; wks = weeks; w/ = with; w/o = without; yr = year; yrs = years

**Quality score numbers: One point (for a total of five) is allocated for meeting (or subtracted for failing to meet) the following criteria: randomized (gains 1 pt if trial is described as such); randomized+ (gains 1 point if method of randomization is described); randomized- (loses 1 point if method of randomization is inadequate); double-blind (gains 1 point if trial is described as such); double-blind+ (gains 1 point if trial provides adequate description of double-blinding); double-blind- (loses 1 point if method of double-blinding is inadequate); dropouts described (gains 1 point if dropouts/withdrawals are described)

*Evidence Table 3: Study Descriptions and Results: Physical Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Parker, Tupling, and Pryor, 1978	SPPG QS: 2 (r, ndb, dd)	N = 99 Age: 41 (range 12-55) 61% female Migraine; ≥ 4 attacks during 2-mo baseline period Chron: 19 yrs Rec: Recruited through the media; U.S.	***Cervical mobilization (oscillation) by medical practitioner or physiotherapist (control condition):*** n = 28 ***Cervical manipulation by medical practitioner or physiotherapist:*** n = 27 ***Cervical manipulation by chiropractor:*** n = 30 2-mo baseline period (HA recording), followed by 2-mo treatment phase, followed by 2-mo post-treatment phase; no more than 2 treatments/wk permitted during treatment phase; 20-mo follow-up results (HA frequency only) reported in Parker, Pryor, and Tupling (1980) Patients' usual drug regimens continued unchanged throughout trial	***HA frequency:*** Mean number of HAs in pre- and post-treatment periods ***HA severity:*** Mean severity scale, pre- and post-treatment (VAS, not described) ***HA duration:*** Mean duration (hrs/attack), pre- and post-treatment ***Disability:*** Mean disability, pre- and post-treatment; scored on scale of 1-5 (usual activities not disrupted; activity possible, but restricted; able to do essentials, but in considerable dis-comfort; most activities impossible; had to remain in bed)	When all three treatment groups were considered together, post-treatment scores were significantly better than pre-treatment scores for HA frequency, severity, and disability, but not for duration. There were no significant differences in any outcomes between the two groups receiving cervical manipulation, considered together, and the group receiving mobilization therapy. When the group receiving chiropractic manipulation was compared with the other two treatment groups, considered together, there was a significant difference in favor of chiropractic manipulation for pain intensity; otherwise there were no significant differences. Comparison of chiropractic manipulation with the control treatment (mobilization) alone showed no significant differences between them. ***Mean HA frequency, pre- and post-treatment:*** Mobilization, 8.7 and 5.7; MD/PT manipulation, 11.4 and 9.9; chiropractic manipulation, 8.5 and 5.1 (no variance data or p-values reported). Follow-up of 73/85 (86%) patients at 20 months showed that HA frequency continued to fall in all three groups (Parker, Pryor, and Tupling, 1980). The ***mean HA frequency for months 18-20*** was 4.9 in the mobilization group, 8.0 in the MD/PT manipulation group and 3.8 in the chiropractic manipulation group (no variance data or p-values reported). ***Mean HA severity, pre- and post-treatment:*** Mobilization, 5.3 and 4.5; MD/PT manipulation, 5.0 and 4.4; chiropractic manipulation, 4.9 and 2.8 (no variance data or p-values reported). No follow-up data were reported.	Dropouts: 14 (14%) Unable to calculate ES because no variance data reported

*Key: AE = adverse event; Assoc = Association; CES = cranial electrotherapy stimulation; Chron = chronicity; cm = centimeter; CrOv = cross-over; db = double-blind; dd = dropouts described; dept = department; ES = effect size; GP = general practitioner; HA = headache; IHS = International Headache Society; MD = medical doctor; med = medication; mg = milligram; min = minute or minutes; mo = month; mos = months; N or n = number of patients; ndb = not double-blind; neuro = neurology; nr = not randomized; N/S = not specified; PT = physiotherapist; QS = quality score; r = randomized; Rec = recruitment setting; SD = standard deviation; SPPG = single-period, parallel-group; TENS = transcutaneous electrical nerve stimulation; TTH = tension-type headache; VAS = visual analog scale; wk = week; wks = weeks; w/ = with; w/o = without; yr = year; yrs = years

**Quality score numbers: One point (for a total of five) is allocated for meeting (or subtracted for failing to meet) the following criteria: randomized (gains 1 pt if trial is described as such); randomized+ (gains 1 point if method of randomization is described); randomized- (loses 1 point if method of randomization is inadequate); double-blind (gains 1 point if trial is described as such); double-blind+ (gains 1 point if trial provides adequate description of double-blinding); double-blind- (loses 1 point if method of double-blinding is inadequate); dropouts described (gains 1 point if dropouts/withdrawals are described)

*Evidence Table 3: Study Descriptions and Results: Physical Treatments**

Study	Methods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Sheftell, Rapoport, and Kudrow, 1989	SPPG QS: 2 (nr, db, dd)	N = 71 Age: N/S % female N/S Common migraine or combination HA Chron: N/S Rec: N/S; U.S.	***Sham cranial electrotherapy stimulation (sham CES), plus either beta-blocker, amitriptyline, or placebo:*** n = N/S ***Cranial electrotherapy stimulation (CES), plus either beta-blocker, amitriptyline, or placebo:*** n = N/S 12-wk baseline period, followed by 12-wk treatment period; CES/sham CES administered for 15 min, 2x/day, for 12 wks; no information provided about concomitant administration of beta-blockers, amitriptyline, and placebo	***Frequency of severe HAs:*** Mean number of severe HA days/12 wks	Limited results were reported only for the group receiving active CES, so it was impossible to compare the effects of CES and sham CES. Investigators reported only that among patients receiving active CES, only those also taking beta-blockers showed a significant reduction in the ***frequency of severe HAs*** compared to baseline or to patients taking placebo ($p<0.05$ for both comparisons). Investigators concluded that CES may enhance the prophylactic effect of beta-blockers, but that further investigation is needed.	Dropouts: 13 (18%) Abstract providing very limited information; no comparison of CES and sham CES possible

*Key: AE = adverse event; Assoc = Association; CES = cranial electrotherapy stimulation; Chron = chronicity; cm = centimeter; CrOv = cross-over; db = double-blind; dd = dropouts described; dept = department; ES = effect size; GP = general practitioner; HA = headache; IHS = International Headache Society; MD = medical doctor; med = medication; mg = milligram; min = minute or minutes; mo = month; mos = months; N or n = number of patients; ndb = not double-blind; neuro = neurology; nr = not randomized; N/S = not specified; PT = physiotherapist; QS = quality score; r = randomized; Rec = recruitment setting; SD = standard deviation; SPPG = single-period, parallel-group; TENS = transcutaneous electrical nerve stimulation; TTH = tension-type headache; VAS = visual analog scale; wk = week; wks = weeks; w/ = with; w/o = without; yr = year; yrs = years

**Quality score numbers: One point (for a total of five) is allocated for meeting (or subtracted for failing to meet) the following criteria: randomized (gains 1 pt if trial is described as such); randomized+ (gains 1 point if method of randomization is described); randomized- (loses 1 point if method of randomization is inadequate); double-blind (gains 1 point if trial is described as such); double-blind+ (gains 1 point if trial provides adequate description of double-blinding); double-blind- (loses 1 point if method of double-blinding is inadequate); dropouts described (gains 1 point if dropouts/withdrawals are described)

*Evidence Table 3: Study Descriptions and Results: Physical Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Solomon and Gugliel-mo, 1985	SPPG QS: 2 (r, ndb, dd)	N = 62 Age: N/S % female N/S Migraine (n = 21), muscle contraction HA (n = 33), or both (n = 8); duration of current HA < half of typical HA at time of treatment Chron: N/S Rec: Patients presented with acute HA at hospital HA unit; U.S.	***Placebo transcutaneous electrical nerve stimulation (TENS) = electrodes in place without electrical stimulation:*** overall n = 22; migraine n = N/S; mixed HA n = N/S ***Subliminal TENS = TENS at a level just below the patient's ability to experience the tingling stimuli:*** overall n = 18; migraine n = N/S; mixed HA n = N/S ***Perceived TENS = TENS at a level just above the patient's ability to experience the tingling stimuli:*** overall n = 18; migraine n = 6; mixed HA n = 1 Patients presented at HA clinic with acute HA underway; TENS (placebo, subliminal, or perceived) applied for 15 min Patients who had taken acute med within 24 hrs before presenting for treatment were excluded	***HA severity:*** Patients graded HA severity on scale of 1-10 before and after treatment, with 10 being the most excruciating pain conceivable; investi-gators analyzed the % of patients in each treatment group whose HA severity was reduced by ≥ 2 points after treatment	**HA severity:** Treatment success was defined as a reduction in HA severity of ≥ 2 pts on a 10-pt scale. Very limited results were reported for migraine and mixed HA patients. 4/7 (57%) of these patients who were treated with perceived TENS achieved success, as did 7/20 (35%) treated with subliminal TENS or placebo (investigators did not report separate results for these two groups). When analyzed for each HA type, the degree of improvement reported with perceived TENS was not significantly greater than that reported with subliminal TENS or with placebo (no p-value reported).	Dropouts: 4 (6%), including 2 patients with migraine; no mixed HA dropouts Treatment modalities used to treat single acute episode of HA Definition of clinical "success" used does not meet our ≥ 50% improvement criterion

*Key: AE = adverse event; Assoc = Association; CES = cranial electrotherapy stimulation; Chron = chronicity; cm = centimeter; CrOv = cross-over; db = double-blind; dd = dropouts described; dept = department; ES = effect size; GP = general practitioner; HA = headache; IHS = International Headache Society; MD = medical doctor; med = medication; mg = milligram; min = minute or minutes; mo = month; mos = months; N or n = number of patients; ndb = not double-blind; neuro = neurology; nr = not randomized; N/S = not specified; PT = physiotherapist; QS = quality score; r = randomized; Rec = recruitment setting; SD = standard deviation; SPPG = single-period, parallel-group; TENS = transcutaneous electrical nerve stimulation; TTH = tension-type headache; VAS = visual analog scale; wk = week; wks = weeks; w/ = with; w/o = without; yr = year; yrs = years

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*Evidence Table 3: Study Descriptions and Results: Physical Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Vincent, 1989	SPPG QS: 2 (r, ndb, dd)	N = 32 Age: 37 90% female Classical or common migraine; ≥ 2 full days of HA/mo Chron: 20 yrs Rec: Referred by neurologists or recruited from British Migraine Assoc; England	***Placebo = sham acupuncture*** (light, surface needling at nonclassical points): n = 15 ***Acupuncture*** (eight classical points used in each treatment): n = 15 4-wk baseline period (HA recording), followed by 6-wk treatment period (one treatment/wk); follow-ups at 6 wks, 4 mos and 1 yr No preventive med permitted; acute med OK	***Pain intensity:*** reported as mean total weekly pain scores (patients graded HA pain 4x/day on a 6-pt scale); mean number of pain-free days and peak HA intensity per week were also reported	***Pain intensity*** was reduced to a significantly greater degree in the true acupuncture group than in the sham acupuncture group ($p<0.03$). Total ***mean weekly pain scores*** in the acupuncture group were 27.8 during the baseline period, 18.8 post-treatment (a 32% reduction from baseline), and 15.7 at 6-wk follow-up (a 44% reduction). In the sham acupuncture group, the corresponding scores were 27.2, 27.9 (a 3% increase), and 23.6 (a 13% reduction). 26/30 patients completing the trial (87%) were followed up at 1 year. Total mean weekly pain scores continued to improve in the true acupuncture group (n = 12) and were significantly lower than in the sham acupuncture group (n = 14): scores were 8.0 vs. 25.1, respectively ($p<0.05$). However, when the mean scores were adjusted for dropouts (by carrying forward scores for the 6-wk follow-up period), the difference between the two groups was not significant. Both treatments increased the mean number of ***pain-free days*** per week and decreased mean ***peak pain scores*** per week, but there was no significant difference between the two groups for these outcomes.	Dropouts: 2 (6%) before completing treatment; 4 more before 1-yr follow-up Unable to calculate ES, because no variance data reported

*Key: AE = adverse event; Assoc = Association; CES = cranial electrotherapy stimulation; Chron = chronicity; cm = centimeter; CrOv = cross-over; db = double-blind; dd = dropouts described; dept = department; ES = effect size; GP = general practitioner; HA = headache; IHS = International Headache Society; MD = medical doctor; med = medication; mg = milligram; min = minute or minutes; mo = month; mos = months; N or n = number of patients; ndb = not double-blind; neuro = neurology; nr = not randomized; N/S = not specified; PT = physiotherapist; QS = quality score; r = randomized; Rec = recruitment setting; SD = standard deviation; SPPG = single-period, parallel-group; TENS = transcutaneous electrical nerve stimulation; TTH = tension-type headache; VAS = visual analog scale; wk = week; wks = weeks; w/ = with; w/o = without; yr = year; yrs = years

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*Evidence Table 3: Study Descriptions and Results: Physical Treatments**

Study	Meth-ods**	Participants	Interventions	Outcomes	Results	Dropouts/ Notes
Wittchen, 1983	SPPG QS: 2 (r, ndb, dd)	N = 30 Age: 39 (range: 24-53) 77% female Common or classical migraine (n = 21), mixed migraine + TTH (n = 7), or cluster (n = 2) (all Ad Hoc) Chron: 57% > 10 yrs Rec: Referred by GP or specialist; Germany	***Wait-list control*** (HA monitoring only; patients seen by psychologist 1x /mo to monitor their recordings and motivate them to continue): n = 10 ***Acupuncture therapy*** (10 sessions over 8 wks, using classical Chinese points): n = 10 ***Psychological therapy*** (Aimed at training patients to observe, experience, and change critical physiological sensations associated with the occurrence of migraine attacks; patients treated in groups of 3-5; six 90-min sessions biweekly + four sessions 1x /wk; treatment administered in three phases [instruction, training, practice in relax. & self-coping skills]): n = 10 4-wk baseline period, followed by an 8-wk treatment period; follow-up at 4 and 8 wks Acute med permitted, but all patients encouraged to reduce their intake	***HA frequency:*** Mean number of HA days/mo ***HA intensity:*** Mean weekly intensity score; patients graded attacks on a scale of 1-5 (slight, moderate, relatively severe, severe, unbearable) ***Frequency of disabling HAs:*** Mean number of days/wk with severe performance impairments	Both active treatments significantly reduced ***HA frequency*** and ***intensity*** from pre- to post-treatment ($p < 0.05$, each group, each outcome); patients in the wait-list group were not significantly improved (no p-value reported). Investigators did not report the results of any between-group comparisons for these outcomes. Similar results (and more data) were reported on pre- to post-treatment changes in the ***frequency of disabling HAs***. In the psychological therapy group, the mean number of days/wk with severe performance impairments (± SD) was reduced from 2.4 (± 3.2) pre-treatment to 1.7 (± 1.8) post-treatment; in the acupuncture group, the reduction was from 3.4 (± 2.0) to 1.6 (± 2.0); and in the wait-list group, from 3.5 (± 5.0) to 3.0 (± 3.7). Investigators did not report the results of any between-group comparisons for this outcome.	Dropouts: 0 2/30 patients had cluster HA Patients referred for trial because of history of severe, long-term HAs

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*Evidence Table 4: Efficacy of Physical Treatments**

Study	Treatment	# Imprv'd/N (%)**	Mean Values N	Before Treatment	After Treatment	% Improvement	OC Measure	Effect Size (ES), Odds Ratio (OR), or p-value
ACUPUNCTURE								
Vs. no treatment (wait-list)								
Wittchen, 1983	Wait-list control	-	10	3.5	3.0	0.14	Freq of disabling HAs	ES, acu vs. WL: 0.31 (-0.57 to 1.2)
	Acupuncture	-	10	3.4	1.6	0.53		
Vs. placebo (sham physical) treatments								
Ceccherelli, Ambrosio, Avila, et al., 1987	Placebo (sham acupuncture)	5/15 (33%)	15	-	-	-	PI	OR, acu vs. plac: 12.9 (2.07 to 79.7)
	Acupuncture	13/15 (87%)	15	-	-	-		
Dowson, Lewith, and Machin, 1985	Placebo (sham TENS)	6/23 (26%)	23	-	-	-	HF	OR, acu vs. plac: 1.33 (0.381 to 4.67)
	Acupuncture	8/25 (32%)	25	-	-	-		
Vincent, 1989	Placebo (sham acupuncture)	-	15	27.2	23.6	0.13	PI	Unable to calculate ES (no variance data reported); $p < 0.03$ (acu better)
	Acupuncture	-	15	27.8	15.7	0.44		

*Key: acu = acupuncture; CES = cranial electrotherapy stimulation; def = definition; diff = difference; ES = effect size; Freq = frequency; HA = headache; HF = headache frequency; HI = headache index; hyper = hyperbaric; Imprv'd = improved; MD = medical doctor; med = medication; mo = month or months; N or n = number of patients; normo = normobaric; n.s. = not (statistically) significant; OC = outcome; OR = odds ratio; PI = pain intensity; plac = placebo; psych = psychological treatment; sublim = subliminal; TENS = transcutaneous electrical nerve stimulation; TTH = tension-type headache; WL = wait-list

**The "# Imprv'd/N (%)" and "N (Mean Value)" may occasionally differ because the efficacy data for each may have been derived at different times in the study (patients may have dropped out, thus reducing the number).

*Evidence Table 4: Efficacy of Physical Treatments**

Study	Treatment	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size (ES), Odds Ratio (OR), or p-value
			N	Before Treatment	After Treatment	% Improvement		
Vs. behavioral treatments								
Wittchen, 1983	Psychological therapy	-	10	2.4	1.7	0.29	Freq of disabling HAs	ES, acu vs. psych: 0.02 (-0.85 to 0.90)
	Acupuncture	-	10	3.4	1.6	0.53		
Vs. pharmacological treatments								
Hesse, Møgelvang, and Simonsen, 1994	Metoprolol + placebo (sham acupuncture)	-	39	-	-	-	HF	Diff between two treatments n.s. (p>0.20)
	Placebo tablets + acupuncture	-	38	-	-	-		
Loh, Nathan, Schott, et al., 1984	Medical treatment	3/25 (12%)	25	-	-	-	HI	OR, acu vs. med: 2.58 (0.565 to 11.8)
	Acupuncture	6/23 (26%)	23	-	-	-		

*Key: acu = acupuncture; CES = cranial electrotherapy stimulation; def = definition; diff = difference; ES = effect size; Freq = frequency; HA = headache; HF = headache frequency; HI = headache index; hyper = hyperbaric; Imprv'd = improved; MD = medical doctor; med = medication; mo = month or months; N or n = number of patients; normo = normobaric; n.s. = not (statistically) significant; OC = outcome; OR = odds ratio; PI = pain intensity; plac = placebo; psych = psychological treatment; sublim = subliminal; TENS = transcutaneous electrical nerve stimulation; TTH = tension-type headache; WL = wait-list

**The "# Imprv'd/N (%)" and "N (Mean Value)" may occasionally differ because the efficacy data for each may have been derived at different times in the study (patients may have dropped out, thus reducing the number).

*Evidence Table 4: Efficacy of Physical Treatments**

Study	Treatment	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size (ES), Odds Ratio (OR), or p-value
			N	Before Treatment	After Treatment	% Improvement		
OTHER PHYSICAL TREATMENTS								
Forsell, Kirveskari, and Kangasniemi, 1985	Placebo (sham occlusal adjustment)	-	17	-	Mean reduction of 1.0 attack/mo	-	HF	Unable to calculate ES (no variance data reported)
Migraine-only	Occlusal adjustment	-	18	-	Mean reduction of 2.0 attacks/mo	-		
Forsell, Kirveskari, and Kangasniemi, 1985	Placebo (sham occlusal adjustment)	-	10	-	Mean reduction of 3.2 attacks/mo	-	HF	Unable to calculate ES (no variance data reported)
Mixed migraine + TTH	Occlusal adjustment	-	10	-	Mean reduction of 4.4 attacks/mo	-		
Myers and Myers, 1995	Normobaric oxygen (control)	1/10 (10%)	10	-	-	-	PI	OR, hyper vs. normo:
	Hyperbaric oxygen	9/10 (90%)	10	-	-	-		75.4 (4.43 to 1283)
Parker, Tupling, and Pryor, 1978	Cervical mobilization by MD or physiotherapist (control)	-	28	8.7	5.7	0.34	HF	Unable to calculate ES (no variance data reported)
	Cervical manipulation by MD or physiotherapist	-	27	11.4	9.9	0.13		
	Cervical manipulation by chiropractor	-	30	8.5	5.1	0.40		

*Key: acu = acupuncture; CES = cranial electrotherapy stimulation; def = definition; diff = difference; ES = effect size; Freq = frequency; HA = headache; HF = headache frequency; HI = headache index; hyper = hyperbaric; Imprv'd = improved; MD = medical doctor; med = medication; mo = month or months; N or n = number of patients; normo = normobaric; n.s. = not (statistically) significant; OC = outcome; OR = odds ratio; PI = pain intensity; plac = placebo; psych = psychological treatment; sublim = subliminal; TENS = transcutaneous electrical nerve stimulation; TTH = tension-type headache; WL = wait-list

**The "# Imprv'd/N (%)" and "N (Mean Value)" may occasionally differ because the efficacy data for each may have been derived at different times in the study (patients may have dropped out, thus reducing the number).

*Evidence Table 4: Efficacy of Physical Treatments**

Study	Treatment	# Imprv'd/N (%)**	Mean Values				OC Measure	Effect Size (ES), Odds Ratio (OR), or p-value
			N	Before Treatment	After Treatment	% Improvement		
Sheftell, Rapoport, and Kudrow, 1989	Placebo (sham CES)	-	-	-	-	-	HF	No usable data reported
	CES	-	-	-	-	-		
Solomon and Guglielmo, 1985	Placebo (sham TENS)	7/20 (35%) (plac + sublim combined)	20 (combined)	-	-	-	PI	Did not calculate OR (def of "success" did not meet ≥ 50% improvement criterion)
	Subliminal TENS							
	Perceived TENS	4/7 (57%)	7	-	-	-		

*Key: acu = acupuncture; CES = cranial electrotherapy stimulation; def = definition; diff = difference; ES = effect size; Freq = frequency; HA = headache; HF = headache frequency; HI = headache index; hyper = hyperbaric; Imprv'd = improved; MD = medical doctor; med = medication; mo = month or months; N or n = number of patients; normo = normobaric; n.s. = not (statistically) significant; OC = outcome; OR = odds ratio; PI = pain intensity; plac = placebo; psych = psychological treatment; sublim = subliminal; TENS = transcutaneous electrical nerve stimulation; TTH = tension-type headache; WL = wait-list

**The "# Imprv'd/N (%)" and "N (Mean Value)" may occasionally differ because the efficacy data for each may have been derived at different times in the study (patients may have dropped out, thus reducing the number).

Appendixes

Appendix A: MEDLINE Search Strategy

Efficacy of headache treatments

1 randomized controlled trials/
2 random allocation/
3 double-blind method/
4 single-blind method/
5 randomized controlled trial.pt.
6 1 or 2 or 3 or 4 or 5
7 animal/
8 human/
9 7 and 8
10 7 not 9
11 6 not 10

12 clinical trial.pt.
13 exp clinical trials/
14 (clin$ adj trial$).tw.
15 ((singl$ or doubl$ or trebl$ or tripl$) adj (blind$ or mask$)).tw.
16 placebos/
17 placebo$.tw.
18 random$.tw.
19 research design/
20 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21 20 not 10

22 comparative-study/
23 exp evaluation studies/
24 follow-up studies/
25 prospective-studies/
26 (control$ or prospectiv$ or volunteer$).tw.
27 22 or 23 or 24 or 25 or 26
28 27 not 10
29 21 not 11
30 28 not (21 or 11)

31 exp headache/
32 11 and 31
33 29 and 31
34 30 and 31

Appendix B: Data Collection Form

Data Abstraction Form ver 5.19.95 Reviewer _____
First Author (last name): _____ Pro-Cite no.: _____ Today's date: ___/___/__

EXCLUDE Why?

Are most or all of the patients in this study in the **pediatric** age group (0-17)? No Yes **-> STOP**

State the **inclusion criteria** (headache diagnoses first)

Headache diagnosis: Migraine Tension-type Cluster mixed other_____

Diagnostic criteria: IHS Ad hoc other none/NS

State the exclusion criteria (headache diagnoses first)

Patient enrollment site *(circle all that apply)*

Primary Care Clinic General Neurology Clinic Headache Clinic Not Stated

Emergency Clinic Pain Clinic Psychology clinic Other _____

Design: Unclear
Single-period parallel-group
Crossover
Matched pair (or paired)

For Cross-over design only-> Was there a significant carry-over effect? Yes No Not Stated
If "yes" then abstract "period one" data **only** as if the trial used a parallel group design.

Instrument to measure bias in pain research reports (Jadad 1996)		Response	Score
1	Was the study described as **randomized** (this includes the use of words such as randomly, random and randomization)?	Yes No	1 0
1a	If the method of generating the randomization sequence was described, was it **adequate** *(table of random numbers, computer-generated, coin tossing, etc.)* or **inadequate** *(alternating, date of birth, hospital number, etc.)*?	Not described/NA Adequate Inadequate	0 1 -1
2	Was the study described as **double-blind**?	Yes No	1 0
2a	If the method of blinding was described, was it **adequate** *(identical placebo, active placebo, etc.)* or **inadequate** *(comparison of tablet vs. injection with no double dummy)*?	Not described/NA Adequate Inadequate	0 1 -1
3	Was there a description of **withdrawals** and **drop-outs**?	Yes No	1 0

Data Abstraction Form ver 5.19.95 Reviewer _____
First Author (last name): _____ Pro-Cite no.: _____ Today's date: ___/___/__

Describe the elements of the study design common to all groups (eg, 4 wk lead in, 12 wk treatment period)	
Brief description of intervention	Details (including dose, duration, timing, etc.)
Intervention 1 (placebo or control or wait-list)	
Intervention 2	
Intervention 3	
Intervention 4	

Patient characteristics (overall: if figures are given by treatment groups, then calculate weighted average)

Age _____ ± _____ or _____ (_____ to _____)
mean ± std dev median and (lower to upper) range

Female (%) _____

Chronicity of H/A d/o ($\bar{x}$, years) _____

HA frequency (#HA/mo) _____

Patient characteristics describe: pre-treatment (trial entry) post-treatment (completion)

Adverse Event Frequency *(%)*	Overall	Intervention 1	Intervention 2	Intervention 3	Intervention 4
Total entered study, n					
Total completed study, n					
Dropouts 2° S/E, (%)					
Dropouts, total, (%)					

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First Author (last name): _____ Pro-Cite no.: _____ Today's date: ___/___/__

Outcome measure Primary or secondary	Def"n (e.g. from 2 or 3 to 0 or 1)	How measured? (e.g. 4 pt scale)	When assessed? (2 hrs, 2 mo)	When were sx recorded? (daily, etc)

BEFORE/Period 1/single-period parallel-group design	Gp 1	Gp 2	Gp 3	Gp 4
Sample size				
Mean				
SD / VAR / SEM *(circle one)*				
AFTER/Period 2				
Sample size				
Mean				
SD / VAR / SEM *(circle one)*				
BEFORE/AFTER comparisons				
Mean				
SD/ VAR / SEM of difference *(circle*				
Test statistic for diff				
Degrees of freedom for test statistic				
p-value of test statistic				
Name of test statistic (e.g.; t, F, etc.)				
BETWEEN GROUP COMPARISONS				
Mean				
SD/ VAR / SEM of difference *(circle*				
Test statistic for diff				
Degrees of freedom for test statistic				
p-value of test statistic				
Name of test statistic (e.g.; t, F, etc.)				
	F statistic	d.f.	p-value	
OVERALL COMPARISON/ANOVA				

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First Author (last name): _____ Pro-Cite no.: _____ Today's date: ___/___/__

Outcome measure Primary or secondary	Def"n (e.g. from 2 or 3 to 0 or 1)	How measured? (e.g. 4 pt scale)	When assessed? (2 hrs, 2 mo)	When were sx recorded? (daily, etc)

	Outcomes (fill in dichotomous outcomes, categories, or ranges for groups as column headers)					Totals
	worst				best	
Treatments	N (%)	N (%)	N (%)	N (%)	N (%)	N (100%)
A						
B						
C						
D						

Outcome measure Primary or secondary	Def"n (e.g. from 2 or 3 to 0 or 1)	How measured? (e.g. 4 pt scale)	When assessed? (2 hrs, 2 mo)	When were sx recorded? (daily, etc)

	worst				best	Totals
Treatments	N (%)	N (%)	N (%)	N (%)	N (%)	N (100%)
A						
B						
C						
D						

Appendix C: Excluded Articles

Articles on behavioral treatments passing the title-and-abstract screen but excluded from consideration in this report

	Reference	Disposition
1	Birbaumer, Gerber, Miltner, et al., 1984	Interventions: Blood volume pulse (BVP) biofeedback (two treatment groups)
2	Birbaumer and Haag, 1982	Interventions: Included treatment compared with two cognitive-behavioral treatments that we would have grouped together (since we excluded BVP, we would have had no comparison group)
3	Blanchard, Kim, Hermann, et al., 1994	Primary focus of trial inappropriate: Studied mechanism by which thermal biofeedback training succeeds or fails, i.e., examined effect of patients' "belief in success" on headache reduction
4	Claghorn, Mathew, Largen, et al., 1981	Interventions: Biofeedback training to decrease skin temperature
5	Cohen, McArthur, and Rickles, 1980	Interventions: Biofeedback training for vasoconstriction of temporal scalp arteries; electromyographic (EMG) biofeedback for forehead cooling; alpha brain wave feedback
6	Drury, DeRisi, and Liberman, 1979	Trial had fewer than five subjects
7	Elmore and Tursky, 1981	Interventions: BVP biofeedback
8	Feuerstein and Adams, 1977	Trial had fewer than five subjects Interventions: Cephalic vasomotor response biofeedback and EMG biofeedback for control of temporal artery
9	Friar and Beatty, 1976	Interventions: BVP biofeedback (temporal artery constriction)
10	Gamble and Elder, 1983	Trial had fewer than five subjects in each treatment group
11	Gauthier, Bois, Allaire, et al., 1981	Interventions: BVP biofeedback (temporal artery constriction, dilation); thermal biofeedback for decreasing skin temperature
12	Gauthier, Doyon, Lacroix, et al., 1983	Interventions: BVP biofeedback (temporal artery constriction, dilation)
13	Gerhards, Rojahn, Boxan, et al., 1983	Interventions: BVP biofeedback
14	Haag and Gerber, 1987	Does not report original research (abstract) Interventions: BVP biofeedback treatment compared with two cognitive-behavioral treatments that we would have grouped together (since we excluded BVP, we would have had no comparison group)
15	Hart, 1984	Results not reported separately for migraine
16	James, Thorn, and Williams, 1993	Results not reported separately for migraine

17	Johansson and Ost, 1987	Intervention: Not appropriate for this study because treatment was designed to test the efficacy of "generalization training" rather than that of thermal biofeedback itself
18	Knapp, 1982	One treatment group had fewer than five subjects
19	Kohlenberg and Cahn, 1981	Intervention: Treatment was "self-help" strategy involving no therapist contact
20	Largen and Mathew, 1981	Intervention: Thermal biofeedback (sham intervention) for decreasing skin temperature
21	Largen, Mathew, Dobbins, et al., 1981	Intervention: Thermal biofeedback for decreasing skin temperature
22	Lisspers and Ost, 1990	Interventions: BVP biofeedback (temporal artery constriction, dilation)
23	Marcus, Scharff, and Turk, 1995	Results not reported separately for migraine
24	Martin, Nathan, Milech, et al., 1989	Results not reported separately for migraine
25	Price and Tursky, 1976	No headache results provided
26	Reich, 1989	Interventions: Could not determine number of patients in the "greater-than" and "less-than 15 treatments" groups for the two interventions we might have been able to study (thermal biofeedback and "microelectrical" therapy); no defined timepoint for the outcome measured; encountered many problems interpreting data
27	Solbach, Sargent, and Coyne, 1992	Duplication of Solbach, Sargent, and Coyne, 1984
28	Szekely, Botwin, Eidelman, et al., 1986	Intervention: Person-centered insight therapy treatment
29	Wauquier, McGrady, Aloe, et al., 1995	Does not report what data patients measured or how headache outcomes were measured
30	Williamson, Monguillot, Jarrell, et al., 1984	Results not reported separately for migraine
31	Winkler, Underwood, Fatovich, et al., 1989	Results not reported separately for migraine

Appendix D: Included Articles

Articles on behavioral treatments passing the title-and-abstract screen and included in this report

1	Anderson, Basker, and Dalton, 1975	21	Kewman and Roberts, 1980
2	Andrasik, Blanchard, Neff, et al., 1984	22	Lacroix, Clarke, Bock, et al., 1983
3	Andreychuk and Skriver, 1975	23	Lake, Rainey, and Papsdorf, 1979
4	Barrios, 1980	24	Machado and Gómez de Machado, 1985
5	Bild and Adams, 1980	25	Mathew, 1981
6	Blanchard, Andrasik, Appelbaum, et al., 1985 Blanchard, Appelbaum, Guarnieri, et al., 1988 – Study reporting 1- and 2-yr follow-up data on patients from above trial	26	McGrady, Wauquier, McNeil, et al., 1994
7	Blanchard, Appelbaum, Nicholson, et al., 1990	27	Mitchell and Mitchell, 1971 - Study 1
8	Blanchard, Appelbaum, Radnitz, et al., 1990	28	Mitchell and Mitchell, 1971 - Study 2
9	Blanchard, Nicholson, Radnitz, et al., 1991	29	Mullinix, Norton, Hack, et al., 1978
10	Blanchard, Theobald, Williamson, et al., 1978 Silver, Blanchard, Williamson, et al., 1979 – One-year follow-up study of patients from above trial	30	Nicholson and Blanchard, 1993
11	Brown, 1984	31	Passchier, van der Helm-Hylkema, and Orlebeke, 1985
12	Daly, Donn, Galliher, et al., 1983 Daly, Zimmerman, Donn, et al., 1985 – One-year follow-up study of patients from above trial	32	Penzien, Johnson, Carpenter, et al., 1990
13	Friedman and Taub, 1984	33	Reading, 1984
14	Gauthier, Côté, and French, 1994	34	Richardson and McGrath, 1989
15	Gauthier, Lacroix, Côté, et al., 1985	35	Sargent, Solbach, Coyne, et al., 1986 Solbach, Sargent, and Coyne, 1984 – Study of subset of patients with menstrual migraine from above trial
16	Holroyd, France, Cordingley, et al., 1995		
17	Holroyd, Holm, Hursey, et al., 1988 Holroyd, Holm, Penzien, et al., 1989 – Three-year follow-up study of the 21 patients successfully treated (achieved ≥ 50% reduction in HA index) in above trial	36	Sorbi and Tellegen, 1984
		37	Sorbi and Tellegen, 1986 Sorbi, Tellegen, and Du Long, 1989 – Three-year follow-up study of patients from above trial
18	Ilacqua, 1994	38	Sovak, Kunzel, Sternbach, et al., 1981
19	Janssen and Neutgens, 1986	39	Wittchen, 1983
20	Jurish, Blanchard, Andrasik, et al., 1983		

Appendix E: Therapies Included in/Excluded from Meta-Analysis

Study	Therapies Included in Meta-analysis[1]								Therapies Excluded from Meta-analysis
	Con-trol	Pla-cebo	RLX	TBF	TBF + RLX	EMG BF	Cog.	TBF + Cog.	
Barrios, 1980			✓		✓		✓		
Bild and Adams, 1980	✓					✓			BVP BF
Blanchard, Appelbaum, Nicholson, et al., 1990	✓				✓[2]			✓[2]	
Blanchard, Appelbaum, Radnitz, et al., 1990	✓	✓			✓			✓	
Blanchard, Nicholson, Radnitz, et al., 1991	✓				✓[3] ✓[4]				
Blanchard, Theobald, Williamson, et al.,1978	✓		✓		✓				
Brown, 1984		✓	✓						RLX (stimulus therapy)
Daly, Donn, Galliher, et al., 1983			✓		✓	✓			
Gauthier, Lacroix, Côté, et al., 1985	✓			✓					BVP BF
Kewman and Roberts, 1980	✓			✓					TBF to decrease temperature
Lake, Rainey, and Papsdorf, 1979	✓				✓	✓		✓	
McGrady, Wauquier, McNeil, et al.		✓			✓[5]				
Mullinix, Norton, Hack, et al., 1978		✓		✓					
Nicholson and Blanchard, 1993	✓							✓	
Richardson and McGrath, 1989	✓						✓[6] ✓[7]		
Sorbi and Tellegen, 1984							✓	✓	
Sorbi and Tellegen, 1986			✓				✓		
Wittchen, 1983	✓						✓		Acupuncture

[1] See last page of table for key to abbreviations and remaining footnotes.

Studies Excluded from Meta-analysis	
Study	**Therapies**
Anderson, Basker, and Dalton, 1975	Hypnotherapy Drug (prochlorperazine [Stemetil®])
Andrasik, Blanchard, Neff, et al., 1984	TBF or RLX (regular contact) TBF or RLX (booster contact)
Andreychuk and Skriver, 1975	Hypnotherapy (self-hypnosis) TBF + RLX BF for alpha enhancement
Blanchard, Andrasik, Appelbaum, et al., 1985	TBF + RLX (home-based) TBF + RLX (clinic-based)
Friedman and Taub, 1984	Control RLX Hypnosis (4 treatments: high/low susceptibility with/without thermal imagery) TBF + RLX
Gauthier, Côté, and French, 1994	TBF (without home practice) TBF (with home practice)
Holroyd, France, Cordingley, et al., 1995	TBF + RLX Drug + beh. (propranolol HCl + TBF + RLX)
Holroyd, Holm, Hursey, et al., 1988	TBF + RLX (home-based) Drug + beh. (ergotamine tartrate + compliance training) (home-based)
Ilacqua, 1994	Control Guided imagery Guided imagery + TBF TBF + RLX
Janssen and Neutgens, 1986	RLX (AT phrases) RLX (PMR)
Jurish, Blanchard, Andrasik, et al., 1983	TBF + RLX (home-based) TBF + RLX (clinic-based)
Lacroix, Clarke, Bock, et al., 1983	RLX TBF EMG BF
Machado and Gómez de Machado, 1985	Control RLX TBF + RLX
Mathew, 1981	Control (abortive ergotamine + analgesics) TBF + RLX + EMG BF 3 drug-only (propranolol, amitriptyline, propranolol + amitriptyline) 3 drug + beh. (propranolol + above BF mix, amitriptyline + above BF mix, propranolol + amitriptyline + above BF mix)
Mitchell and Mitchell, 1971 (Study 1)	Control RLX RLX + Cog. (combined desensitization)
Mitchell and Mitchell, 1971 (Study 2)	Control RLX + Cog. (systematic desensitization) Cog. (combined desensitization with no previous drug treatment) Cog. (combined desensitization with previous drug treatment)

[1] See last page of table for key to abbreviations and remaining footnotes.

Passchier, van der Helm-Hylkema, and Orlebeke, 1985	Control Cog. + RLX Cog. + RLX + TBF Cog. + RLX + BVP BF
Penzien, Johnson, Carpenter, et al., 1990	TBF + RLX + Cog. Drug (propranolol [Inderal® LA])
Reading, 1984	Placebo TBF Skin conductance BF EMG BF
Sargent, Solbach, Coyne, et al., 1986	Control RLX TBF EMG BF
Sovak, Kunzel, Sternbach, et al., 1981	TBF + RLX Drug (propranolol + analgesics)

[1] Abbreviations: AT = autogenic; beh. = behavioral; BF = biofeedback; BVP = blood volume pulse; cog. = cognitive; EMG = electromyographic; HCl = hydrogen chloride; PMR = progressive muscle relaxation; RLX = relaxation; TBF = thermal biofeedback

[2] Home-based

[3] With home practice

[4] Without home practice

[5] Contained EMG BF component, but classified as TBF + RLX because EMG BF component had fewer sessions

[6] Minimal-therapist treatment

[7] Clinic-based treatment