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## What does the evidence show? Efficacy of behavioural treatments for recurrent headaches in adults

**Abstract** Behavioural treatments (predominantly biofeedback, relaxation and cognitive-behavioural) have been utilised in headache management for nearly 4 decades. This paper examines their clinical efficacy, drawing upon 2 primary sources of evidence: meta-analytic and evidenced-based reviews. Behavioural treatments have demonstrated efficacy and have been endorsed by various reviewing groups, such as the US Headache Consortium. Outcomes from behavioural treatments appear to endure over longer-term follow-up intervals as well. Meta-analyses comparing behavioural and pharmacological treatments have revealed similar levels of outcome. The article closes with a brief discussion of methods investigators are exploring to make behavioural treatments more available and affordable to headache patients.

**Key words** Migraine • Tension-type headache • Behavioural treatment • Biofeedback • Efficacy

### Introduction

As outlined in a prior article in this series [1], there are three basic approaches to behavioural treatments for recurrent headache disorders. These approaches are designed (a) to promote general overall relaxation either by therapist instruction alone (e.g., progressive muscle relaxation, autogenic training, meditation) or therapist instruction augmented by feedback of various physiological parameters indicative of autonomic arousal or muscle tension to help fine tune relaxation, termed biofeedback-assisted relaxation (e.g., temperature, electromyographic or electrodermal biofeedback); (b) to control, in a more direct fashion, those physiological parameters assumed to underlie headache (e.g., for migraine, cerebral blood flow and electroencephalographic biofeedback, primarily using contingent negative variation to target parameters reflective of problems with habituation; for tension-type headache when muscular abnormalities are in evidence, muscle tension levels); and (c) to enhance abilities to manage stressors and stress reactions to headache (e.g., termed variously as cognitive therapy, cognitive behaviour therapy, stress management and stress coping training) [2]. Headache is a complex problem that often can require a multi-dimensional, multi-disciplinary approach [3]. Although the above-mentioned techniques are most often applied in combination and with other forms of treatment and ongoing medical care in the clinical setting, they will be reviewed here in somewhat isolated fashion to examine their independent effects.

### Evidence base for migraine headache

Meta-analyses

The first behavioural interventions were introduced nearly four decades ago. At present, the number of published

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studies is extensive, making study-by-study reviews daunting. This has led many reviewers over the years to examine efficacy by the quantitative procedure of meta-analysis, where results from disparate studies can be aggregated into a single statistical analysis and comparisons made on a somewhat level playing field. Table 1 contains a listing of the various meta-analyses of behavioural treatments for migraines in adults conducted to date.

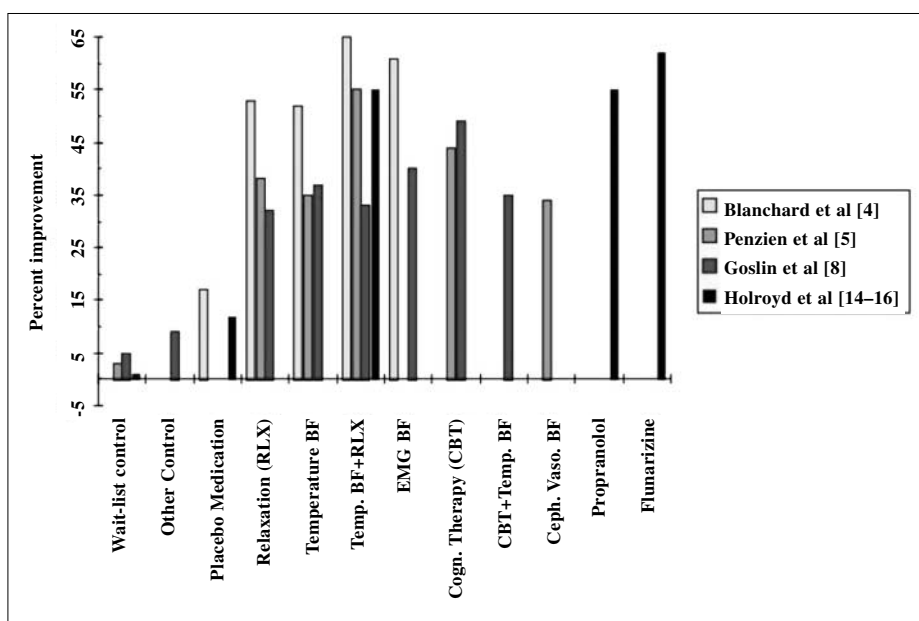
Early meta-analyses were very inclusive, excluding few of the available studies. In these analyses, less well designed studies (single group outcome, nonrandomised, nonpeer-reviewed) were included along with expertly designed studies. The main entrance criterion was a minimal sample size per treatment condition. Also, percentage improvement on headache indices served as the main measure of outcome (wherein disparate indices were lumped together and not analysed separately). The more recent analyses have been much more selective about the studies

permitted to enter analysis. For example, one of the more recent migraine meta-analyses, sponsored by the US Agency for Healthcare Research and Quality (AHRQ) [8], located 355 behavioural and physical treatment (acupuncture, TENS, occlusal adjustment, cervical manipulation and hyperbaric oxygen) articles, 70 of which consisted of controlled trials of behavioural treatments for migraine. Only 39 of these trials met criteria for inclusion in the analysis. Figure 1 shows the findings from this and three other meta-analyses to provide a sense of their findings. This figure also contains results from similar quantitative analyses conducted for various prophylactic medications [14–16]. For these latter meta-analyses results from drug trials evaluating prophylactic medications were extracted for comparison, as few studies have included behavioural and medication treatments in direct comparisons. Considering all meta-analyses to date, the behavioural treatments have been found to be superior to various control conditions, with no major differences emerging between the behavioural treatments and the medications being compared to them. These meta-analytic findings of comparable outcomes for behavioural and medication treatments are consistent with the findings from the few direct comparisons that have been conducted for migraine headache [17–22].

Most recent meta-analyses (beginning with Goslin et al. [8]) have incorporated “effect size” estimates, or measures that use standardised differences between means, for determining effectiveness, and have performed analyses that examine more than outcome alone. The most recent and most extensive meta-analysis for migraine to date [9], one that focused mainly on biofeedback, merits more extended discussion. These authors began with a detailed search of databases compiled by Medline, PsychInfo, Psyn dex and the Cochrane library, followed by manual searches (examining reference lists for all identified arti-

**Table 1** Listing of meta-analyses of behavioural treatments for migraine and tension-type headache

Migraine headache	
Blanchard, Andrasik, Ahles, Teders & O’Keefe (1980) [4]	
Penzien, Holroyd, Holm & Hursey (1985) [5]	
Blanchard & Andrasik (1987) [6]	
Haddock, Rowan, Andrasik, Wilson, Talcott & Stein (1996) [7]	
Goslin, Gray, McCrory, Penzien, Rains & Hasselblad (1999) [8]	
Nestoriuc & Martin (2006) [9]	
Tension-type headache	
Blanchard, Andrasik, Ahles, Teders & O’Keefe (1980) [4]	
Holroyd & Penzien (1986) [10]	
Bogaards & terKuile (1994) [11]	
Haddock, Rowan, Andrasik, Wilson, Talcott & Stein (1996) [7]	
McCrory, Penzien, Hasselblad & Gray (2001) [12]	



**Fig. 1** Combined meta-analyses of behavioural and pharmacological treatments for migraine. Percent improvement scores by treatment condition. Portions adapted from Penzien et al. [13]. Reproduced with permission from Springer Publishing

cles and all prior published meta-analytic reviews). They uncovered 800 matches in English or German, with 86 identified as outcome studies (nearly 20 more in the years that had ensued since the report by Goslin et al. [8]). Fifty-five consisted of randomised controlled trials or studies including pre- and post-assessments. Statistical comparisons were made between the various types of biofeedback investigated (temperature, blood volume pulse (BVP), electromyographic, and a combination of temperature, electromyographic and relaxation) and between all biofeedback studies lumped together and various controls and active treatments (no treatment/waiting list control, placebo control, relaxation alone and pharmacotherapy). This meta-analysis, notably, was the first to perform intention-to-treat analyses to examine potential biasing effects due to attrition. Effect sizes for the resultant comparisons are presented in Tables 2 and 3.<sup>1</sup>

All forms of biofeedback treatment were found to produce significant medium to large effect sizes pre vs. post (see Table 2). When intention-to-treat analyses were conducted, wherein dropouts were included and considered as treatment failures, effects still held. BVP biofeedback has not been included in most prior meta-analyses. In early analyses there were too few investigations employing BVP, while in some of the later evaluations BVP was excluded because it is thought to be quite complex and less likely to be used in clinical settings. Advances in instrumentation have minimised the attendant complexities, and its use is increasing. Thus, it is of interest to point out that BVP (elsewhere referred to as cephalic vasomotor) biofeedback yielded the largest effect size overall. The significant treatment effects held for all pain indices exam-

ined: headache frequency, duration, and intensity, headache-index (a composite measure), and medication-index. However, the improvements in medication-index were smaller than those for the primary measures of headache improvement (frequency and duration). This meta-analysis, it should be noted, is the first to examine various indices separately. Biofeedback fared well when compared to various inactive and active comparison conditions (see Table 3), with improvement levels being equivalent for biofeedback and relaxation therapies.

Nestoriuc and Martin [9] additionally examined outcomes for psychological variables (anxiety, depression and self-efficacy), the durability of effects (wherein the follow-up periods ranged from 6 to 60 months), as well as potential predictors and moderators of treatment effects, which included considerations of design quality (rated with respect to a 12-item validity scale). Improvements for depression and self-efficacy yielded medium to large effect sizes, while the effects for anxiety were small to medium. Aggregating across the varied follow-up intervals yielded medium to large effect sizes, supporting a high level of maintenance of effects. The final set of analyses performed by Nestoriuc and Martin concerned identification of factors associated with response to treatment. Here it was found that outcomes, both initial and longer-term, were significantly greater when home practice accompanied treatment (vs. treatment that was restricted to the office setting alone). Gender and age were related to initial outcome but not to longer-term results. Chronicity, however, was negatively related both to short- and long-term outcome. Finally, for both short- and long-term effects, studies with higher methodological rigour yielded lower overall effects.

**Table 2** Effect size indices (weighted mean) for comparisons of various biofeedback modalities. Data extracted from Nestoriuc and Martin [9]

Modality	Total patients treated	Effect size	Significance
Temp-BF	221	0.52	Medium to large
BVP-BF	306	0.68	Medium to large
EMG-BF	105	0.50	Medium to large
Combined	777	0.60	Medium to large

*Temp-BF*, temperature biofeedback; *BVP-BF*, blood volume pulse biofeedback; *EMG-BF*, electromyographic biofeedback; *combined*, Temp-BF+relaxation+EMG-BF

**Table 3** Effect size indices (weighted means) for comparisons of biofeedback to various control and active treatment conditions. Data extracted from Nestoriuc and Martin [9]

Comparison	Total patients treated	Effect size	Significance
BF vs. no-treatment control	574	0.45	Medium
BF vs. placebo control	340	0.25	Small to medium
BF vs. relaxation	136	0.10	Not significant
BF vs. pharmacotherapy	52	0.30	Small to medium

<sup>1</sup>Readers may find it of interest to note that 55 trials conducted with paediatric migraine were uncovered but were excluded from analysis as this study concerned only adults with migraine. The paediatric literature will not be reviewed here.

## Efficacy reviews

In addition to meta-analytic approaches, a second form of evaluation has emerged for analysing treatment efficacy. Over the years, various groups have assembled expert panels to conduct evidence-based reviews, wherein rigorous methodological criteria are used to evaluate every study under consideration. Evidence-based analyses have been performed by the Division 12 Task Force of the American Psychological Association [23], the US Headache Consortium (composed of the American Academy of Family Physicians, American Academy of Neurology, American Headache Society, American College of Emergency Physicians, American College of Physicians-American Society of Internal Medicine, American Osteopathic Association and National Headache Foundation) [24], the Cochrane collaboration, and the Association for Applied Psychophysiology and Biofeedback [25]. Criteria utilised are similar. Those used by the Association for Applied Psychophysiology and Biofeedback, among the most rigorous, are listed in Table 4 for purposes of illustration [26].

The US Headache Consortium evidentiary panel consisted of professionals from multiple disciplines and societies

and, thus, their recommendations take on particular weight. Their findings are of further note because of the variety of nonpharmacological treatments included, many of which had been ignored in prior evaluations (e.g., hypnosis, acupuncture, TENS, etc.). Table 5 summarises their recommendations pertaining to behavioural interventions for migraine. Here the evidence for various behavioural treatments is judged quite favourably. Finally, the Consortium pointed out that behavioural treatments might be particularly well suited for certain types of patients, which are listed in Table 6.

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## Evidence base for tension-type headache

Tension-type headache is a common form of headache, and it, too, has received considerable attention in the literature (see Table 1 for a listing of meta-analytic reviews conducted to date). The most extensive review conducted to date is that from the AHRQ in conjunction with the Foundation for Chiropractic Education and Research [12]. This meta-analytic review, like its companion review for migraine conducted by AHRQ [8], was exhaustive, searching out the

**Table 4** Criteria for determining efficacy of treatment. From LaVaque et al. [26]

*Level 1:* Not empirically supported: supported only by anecdotal reports and/or case studies in nonpeer-reviewed venues.

*Level 2:* Possibly efficacious: At least one study of sufficient statistical power with well identified outcome measures, but lacking randomised assignment to a control condition internal to the study.

*Level 3:* Probably efficacious: Multiple observational studies, clinical studies, wait list controlled studies, and within-subject and intra-subject replication studies that demonstrate efficacy.

*Level 4:* Efficacious: (a) In a comparison with a no-treatment control group, alternative treatment group, or sham (placebo) control utilising randomised assignment, the investigational treatment is shown to be statistically significantly superior to the control condition or the investigational treatment is equivalent to a treatment of established efficacy in a study with sufficient power to detect moderate differences. (b) The studies have been conducted with a population treated for a specific problem, for whom inclusion criteria are delineated in a reliable, operationally defined manner. (c) The study used valid and clearly specified outcome measures related to the problem being treated. (d) The data are subjected to appropriate data analysis. (e) The diagnostic and treatment variables and procedures are clearly defined in a manner that permits replication of the study by independent researchers. (f) The superiority or equivalence of the investigational treatment have been shown in at least two independent research settings.

*Level 5:* Efficacious and specific: The investigational treatment has been shown to be statistically superior to credible sham therapy, pill or alternative bona fide treatment in at least two independent research settings.

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**Table 5** US Headache Consortium recommendations for behavioural treatment of migraine [24]

*Grade A evidence:* Relaxation training, thermal biofeedback combined with relaxation training, electromyographic biofeedback and cognitive-behavioural therapy may be considered as treatment options for prevention of migraine.

*Grade B evidence:* Behavioural therapy may be combined with preventive drug therapy to achieve added clinical improvement for migraine.

*Grade C evidence:* Evidenced-based treatment recommendations are not yet possible regarding the use of hypnosis, acupuncture, TENS, cervical manipulation, occlusal adjustment and hyperbaric oxygen as preventive or acute therapy for migraine. For hyperbaric oxygen treatment, even if further studies confirmed efficacy results presented above, the lack of availability would limit practical clinical application of this treatment.

Quality of evidence grading system used:

A. Multiple well designed randomised clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings.

B. Some evidence from randomised clinical trials supported the recommendation, but the scientific support was not optimal. For instance, either few randomised trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation. An example of the last point would be the case where trials were conducted using a study group that differed from the target group for the recommendation.

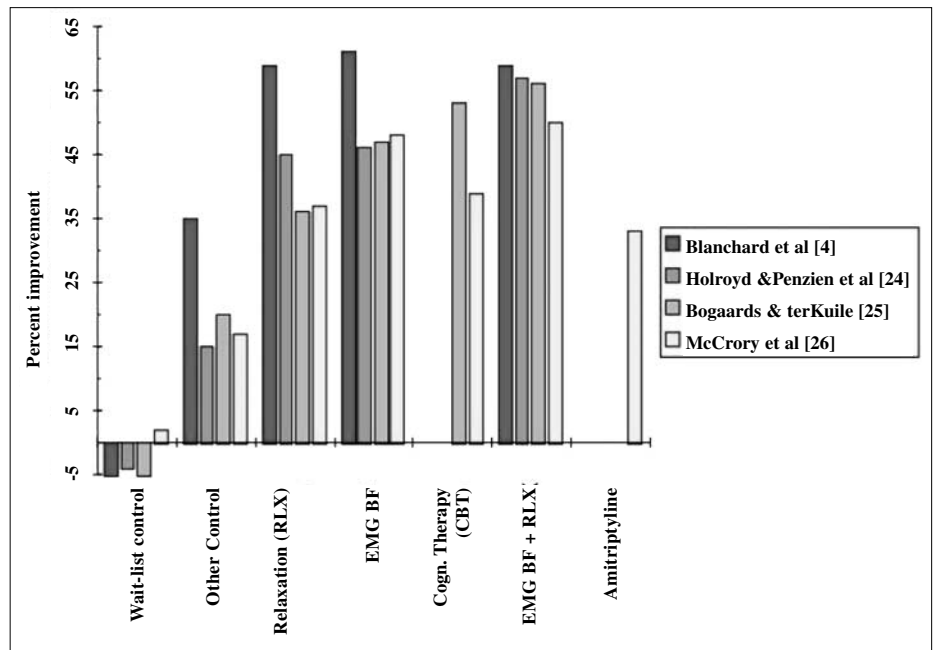
C. The US Headache Consortium achieved consensus on the recommendation in the absence of relevant randomised controlled trials.

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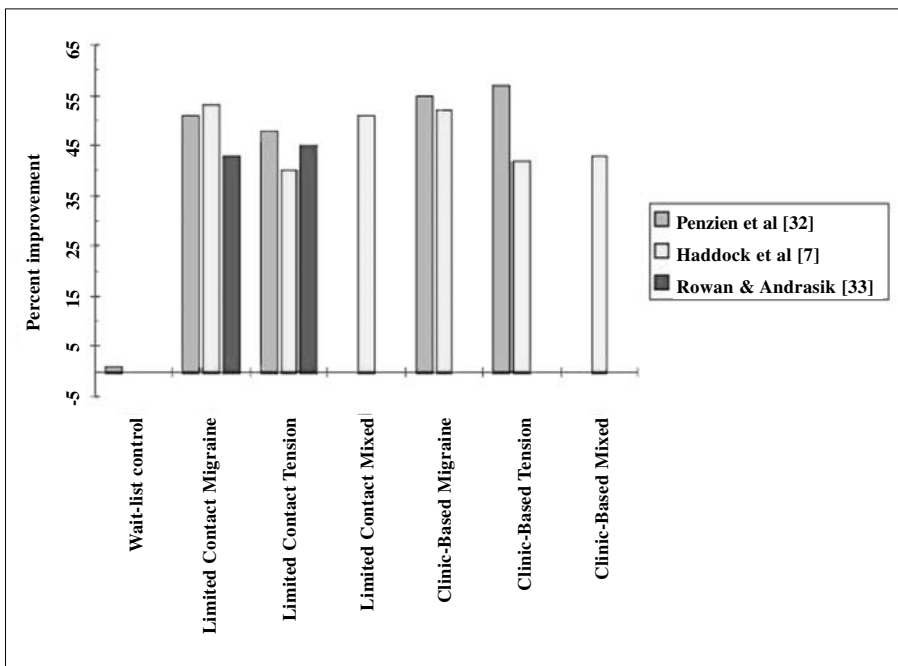
**Table 6** Particularly suited for behavioural treatments [24]

Patients who:

- (a) Have a preference for nonpharmacological interventions;
- (b) Display a poor tolerance for specific pharmacological treatments;
- (c) Exhibit medical contraindications for specific pharmacological treatments;
- (d) Have insufficient or no response to pharmacological treatment;
- (e) Are pregnant, are planning to become pregnant, or are nursing;
- (f) Have a history of long-term, frequent or excessive use of analgesic or acute medications that can aggravate headache problems (or lead to decreased responsiveness to other pharmacotherapies);
- (g) Exhibit significant stress or deficient stress-coping skills.



**Fig. 2** Combined meta-analyses of behavioural and pharmacological treatments for tension-type headache. Percent improvement scores by treatment condition. Portions adapted from Penzien et al. [13]. Reproduced with permission from Springer Publishing



**Fig. 3** Combined meta-analyses of clinic- and limited- contact behavioural treatments for migraine, mixed, and tension-type headaches. Percent improvement scores by treatment condition. Portions adapted from Penzien et al. [13]. Reproduced with permission from Springer Publishing

most well controlled published reports available. The panelists identified 107 articles addressing some form of behavioural treatment for tension-type headaches, published between 1966 and 1999, 35 of which were prospective, randomised controlled trials that employed stringent data analytic plans. McCrory and colleagues [12] also searched for trials evaluating amitriptyline, finding only three at that time that met their rigid inclusion criteria. Results from this meta-analysis, along with two others for comparison purposes, are found in Figure 2. As with the migraine meta-analyses, the behavioural treatments were significantly better than the control conditions, but there were no differences between the various behavioural approaches and amitriptyline. The most recent direct comparison between behavioural treatment and amitriptyline found similar rates of improvement for them (35% vs. 38% of patients being meaningfully improved, respectively), with the gains being achieved more quickly for the medication condition [27]. The greatest amount of improvement (64% of patients), however, resulted from a combination of the two treatments showing a clear additive effect.

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### Summary and concluding remarks

Consideration of the above-reported findings leads to the following conclusions. First, relaxation, biofeedback and cognitive therapy lead to significant reductions in headache activity, ranging from 30% to 60%. Second, conversely, there are a fair number of patients who are nonresponders or partial responders (approximately 40%–70%). Prediction of treatment response and careful treatment planning become particularly important when attempting to improve upon this outcome. Certain headache types have proven to be particularly difficult to treat by behavioural approaches (those characterised by medication overuse and a presentation that is chronic, daily and unwavering, and those diagnosed as cluster or post-traumatic; these forms are difficult to manage by medication as well) [28]. Third, improvements for behavioural treatments exceed those obtained for various control conditions (waiting-list, medication placebo, psychological placebo). Fourth, behavioural treatments produce benefits similar to those obtained for pharmacological treatments. Fifth, combining various behavioural and pharmacological treatments can increase overall effectiveness, but when and how to do so to maximise effectiveness has received scant attention [13]. Stratification strategies for behavioural treatments are sorely needed, as the net gain of adding a second treatment modality beyond a single treatment sometimes is relatively small. Research into the prediction of treatment response may help shed light on this topic and allow clinicians to maximise therapeutic gains. Sixth, evidence from the meta-analyses suggests that the effects for

behavioural therapies endure over time. A number of individual studies have found substantial maintenance of treatment gains, at least among those who respond initially, for periods of up to seven years post-treatment [29], and that these effects are maintained whether further contact is provided (booster sessions) or not [30].

Seventh, most studies of behavioural interventions have included patients that continued their consumption of any number of pharmacological agents while undergoing behavioural interventions. It is assumed that the patients (and investigators) have not considered these concurrent medications to be optimally effective or the patients would not be seeking additional treatment. Nonetheless, many of the behavioural trials perhaps should be construed as behavioural plus medication treatments or behavioural treatment following nonoptimal pharmacological treatment. Only a very few studies have systematically isolated pure treatments [17–22, 27, 31] and these have produced findings similar to those that have been reported in the meta-analytic comparisons (similar outcomes).

Despite these encouraging findings of the efficacy for behavioural treatments, these treatments are not yet widely available. Some possible reasons for this are their relative high cost due to the number of patient–therapist contacts typically required and, in the case of biofeedback, the special equipment and the training needed for properly operating the equipment. This has led investigators to explore whether these behavioural treatments can be offered in more time-efficient and cost-economical platforms. Two such alternatives have emerged, both achieving favourable findings. The first involves reducing the amount of direct face-to-face contact with patients. To accomplish this, patient education materials (treatment manuals and audiocassettes typically) are prepared so that the patient can conduct much of the training at home. In published trials, treatments that formerly required as many as 16 or so sessions have been trimmed back to 3–5 office sessions with no appreciable loss in effectiveness. The time that patients need to spend in reading about and practising their behavioural skills remains extensive. Thus, the cost savings are in terms of reduced travel time for the patient and reduced costs for office visits. This also leaves behavioural therapists with increased time to help other patients in need. To bridge the time between appointments and to provide advice as needed, treatment may be supplemented by brief telephone contacts. Meta-analyses support the clinical utility of such limited-contact or home-based behavioural treatments, in that findings have been very similar to those obtained for in-clinic treatments (see Fig. 3, which presents findings from available reviews). It is likely that certain types of patients will be less responsive to limited contact treatments (such as chronic forms of headache and headache complicated by medication overuse), but this has received minimal attention to date [28, 34]. Also, incorporating messages that are tailored to

the specific symptom presentation and progress of patients may lead to further gains [35].

The second format involves administration to groups of patients, allowing therapists to treat a larger number of patients in a given unit of time and the session charges to be allocated over a number of patients. Group treatments also afford a greater level of support and understanding. Although group approaches seem a logical way to proceed, few investigators have reported on their utility [36]. Other creative outlets for behavioural treatments beginning to be explored concern the worksite [37], internet [38–41] and mass media [42].

Headaches accompanied by medication overuse are increasingly being recognised as particularly difficult to treat. A trial conducted with patients who had chronic migraine accompanied by medication overuse produced evidence suggestive of a distinct advantage for adding a behavioural treatment to routine medical care (inpatient medication withdrawal of offending substances followed by appropriate prophylactic medication) [43]. At a 1-year follow-up evaluation those patients treated by medication alone were found to be similar to those patients who additionally received a trial of biofeedback-assisted relaxation. However, at the 3-year follow-up, the combined treatment group showed a distinct advantage. Those receiving behavioural treatment recorded fewer days of headache, reported less consumption of analgesics, and evidenced less relapse than those receiving medication alone (12.5% vs. 42.1%). It may be that the training in behavioural management techniques provided patients with an effective alternative to relying upon acute palliative or abortive medication for dealing with headache exacerbations.

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