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SYSTEMATIC REVIEW

# Headaches treatment with EMG biofeedback: a focused systematic review and meta-analysis

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## ABSTRACT

INTRODUCTION: The aim of this paper was to present an up-to-date evaluation of the efficacy of EMG-biofeedback (EMG-BFB) for primary headaches and to address possible mediators of outcome.

EVIDENCE ACQUISITION: PubMed, Scopus, Embase and Pedro databases were searched from inception to May 1, 2023. All randomized controlled trials (RCT) studies using an EMG-BFB to treat headache have been included in this systematic review. The current systematic review was performed following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations and was registered in the PROSPERO database (CRD42022312827). Methodological quality was assessed through the Risk of Bias tool 2 (RoB 2). The effect sizes and 95% confidence interval (CI) were calculated by random-effect models on frequency, intensity, and duration variables. Egger regression and the Begg-Mazumdar rank correlation test were used for publication bias.

EVIDENCE SYNTHESIS: A total of 3059 articles were identified through the database searches. 29 articles, involving 1342 participants, met the inclusion criteria for the systematic review; of them, 4 were included in the meta-analysis. Ten studies reported a significant improvement in the EMG-BFB group with respect to the control group. Meta-analyses show a reduction in the intensity of attacks in patients subjected to EMG-BFB (ES 0.21 [(95% CI=-0.02; 0.44), P value=0.07] based on 293 patients).

CONCLUSIONS: EMG-BFB represents a non-pharmacological approach to headache treatment as shown via qualitative synthesis, despite not impressive results, this technique can be particularly useful in paediatric or in adult patients who cannot undergo drug therapies. Quantitative synthesis revealed a promising effect in the intensity of headaches attacks. Moreover, no significant effect was found about the effectiveness of EMG-BFB in the reduction of frequency and durations of headache attacks. Future studies with new multimodal technologic assessment and following RCT guidelines can unmask the potentiality of EMG-BFB in the treatment of headache.

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KEY WORDS: Headache disorders; Migraine disorders; Tension-type headache; Neurofeedback.

## Introduction

Primary headaches are a public health problem with socio-economic burden and related disability. In the context of all types of primary headaches, tension-type headache and migraine are the most common with a prevalence about 38% for tension-type headaches and 12% for migraine, while the trigeminal autonomic cephalalgias have less impact in the general population.[1, 2] Furthermore, in relation to its debilitating symptoms, primary headaches and in particular migraine have an important impact on the daily life of people, interfering negatively with playful and recreational activities as well as with the work productivity with heavy repercussions on the global economy.[3] Therefore, the headache-related disability due to pain and associated headache symptoms justify acute or preventive treatments, or both, optimizing treatments with tailored approaches.[4]

Between nonpharmacologic preventive therapeutic approaches, cognitive behavioral treatments (CBT) have the main domain in the prophylaxis of primary headaches attacks. A recent meta-analysis reported the following main CBTs for headache: Biofeedback, Mindfulness, patient's education, relaxation/cognitive restructuring techniques, keeping a headache diary.[5] Among these, Biofeedback may prove effective to decrease severity, frequency, and disability of chronic headaches and migraine in adults[6, 7] as well as in children.[4] Biofeedback is an established nonpharmacologic technique that assumes the meaning of a specific approach used to modulate a body function and then commonly used also in the treatment of primary headaches.[6] The effectiveness of Biofeedback in limiting severity and frequency of primary headaches (migraine) was linked to muscular relaxation obtained by reducing affective stress and by modulation of the oxidative stress, a process recognized as characterizing migraine patients.[7] Several types of biofeedback can be applied: best effects are evident with temperature- and electromyographic (EMG)-biofeedback (EMG-BFB).[8, 9]

EMG-BFB is based on a monitoring instrument which detects, amplifies, and displays ongoing physiologic involuntary processes, inducing the patient to learn how to modify and interact with them.[9] Therefore, conscious pain control can be conditioned. In the EMG-BFB, the information of electrical muscular activity is measured by electrodes, amplified, and given in real time to the subject in visual or acoustic modality.[8] This mind-body technique may be used to treat a wide range of mental and physical health problems, forcing patients to take an active role to reach their wellbeing. EMG-BFB-related approaches to headache therapy fall into two broad categories: general EMG-BFB techniques and methods linked more directly to the pathophysiology underlying headache. General biofeedback-assisted relaxation techniques for headache have been evaluated extensively by expert panels and in meta-analyses and found to be potentially useful for enhancing patient outcomes, albeit with the limit of a lack of significant relief in a sizable number of patients.[10] Recently Andrasik and colleagues highlighted that randomized controlled trials (RCT) should include adequate-length follow-up and should address changes in biomarkers of disease and other possible mediators of outcome.[10] The objective of the present systematic review is to present an up-to-date evaluation of the efficacy of EMG-BFB for primary headaches (*i.e.*, migraine and tension-type headache) and to address possible mediators of outcome.

## Evidence acquisition

The current systematic review and meta-analysis was performed following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations[11] and was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (CRD42022312827). Studies eligible for review were identified through electronic databases such as Pubmed, Scopus, Embase and PEDro from inception to 1st May 2023. We combined the search strategy of MESH terms and free text terms for the topics of ("Headache Disorders" OR "Migraine Disorders" OR "Cluster Headache" OR "Tension-Type Headache") and ("Electromyography" OR "Biofeedback, Psychology" OR "EMG"). The complete search terms and strategy are provided in Supplementary Digital Material 1, Supplementary Text File 1. The search was limited to studies written in English; grey literature was excluded from the search process. Studies were considered eligible for review if they met the following inclusion criteria: 1) performed on a population with headache; 2) treatment through EMG-biofeedback; 3) randomized clinical trials design; 4) full-length text in English language. Studies were excluded based on the following exclusion criteria: 1) other biofeedback method; 2) conference papers; 3) headache due to other conditions (*i.e.*, pregnancy, traumatic injury, etc.); 4) EMG-biofeedback treatment combined with pharmacological treatment different from subject's usual therapy. All results have been uploaded to an online database and screened simultaneously and independently by three reviewers (MR, CB, SM) about title and abstract. At the end of the process, in the event of no agreement, a fourth reviewer (AB) was consulted. Subsequently, all reviewers independently assessed the full text of the selected articles. Following information from the studies have been reported simultaneously by two reviewers (AB, TL): surname of the first author and year of publication; study objectives; electoral criteria; description of the sample (age and sex); level of disability; study design (frequency and duration of treatments); control group; outcome measures; EMG-biofeedback characteristics; results and conclusions. Data of the selected study have been presented in a synoptic table. Methodological quality of the individual studies was assessed in accordance with the Risk of Bias tool 2.0 (RoB2)[12] by two independent reviewers (AB and MR). Potential discrepancies in quality assessment were resolved through consensus or through discussion with a third reviewer (AMC) in accordance with the recommendation of Cochrane Reviews.[13] RoB 2 is structured into five set of domains of bias: 1) “Risk of bias arising from the randomization process”; 2) “Risk of bias due to deviations from intended interventions’”; 3) “Missing outcome data”’; 4) “Risk of bias in measurement of the outcome”; 5) “Risk of bias in selection of the reported result.” Within each domain, a series of “signaling questions”’ aimed to elicit information about features of the trial that are relevant to determine the risk of bias. Judgement could be “Low” or “High” risk of bias or can express “Some concerns.” The overall risk of bias was achieved following the help of the decision algorithm provided by Cochrane.[12]

The randomized clinical trials that reported exhaustive data for the headache frequency, intensity, and duration variables were selected for the meta-analysis. We pooled individual study data using ProMeta3® (Internovi, Milan, Italy) software. A random effects model meta-analysis was employed. Hedge’s g effect size (ES) was calculated through mean, standard deviation (SD) and sample size. Heterogeneity between studies was assessed by computing the Q-statistics and $I^2$. Substantial statistical heterogeneity was assumed if the Q-statistic was significant (P value $<0.05$) and the $I^2$ value was higher than 75%. Characterization of variances across studies were calculated as no heterogeneity, low heterogeneity, moderate heterogeneity, and high heterogeneity, respectively for the $I^2$ values of 25%, 25% to 50%, 50% to 75%, >75%.[13] To investigate publication bias, we performed the Egger’s regression test and the Begg-Mazumdar’s Test.[14]

## Evidence synthesis

A total of 3059 articles have been found. After the duplicate removal (973), 2086 articles were screened. After screening of titles and abstracts, 1998 articles have been excluded, because they do not meet the inclusion criteria. A total of 88 full-text articles have been examined. Fifty-nine studies have been excluded during full-text check, in conclusion 29 articles[15-43] have been included in the systematic review (Flow-chart of studies screening are available in Figure 1).

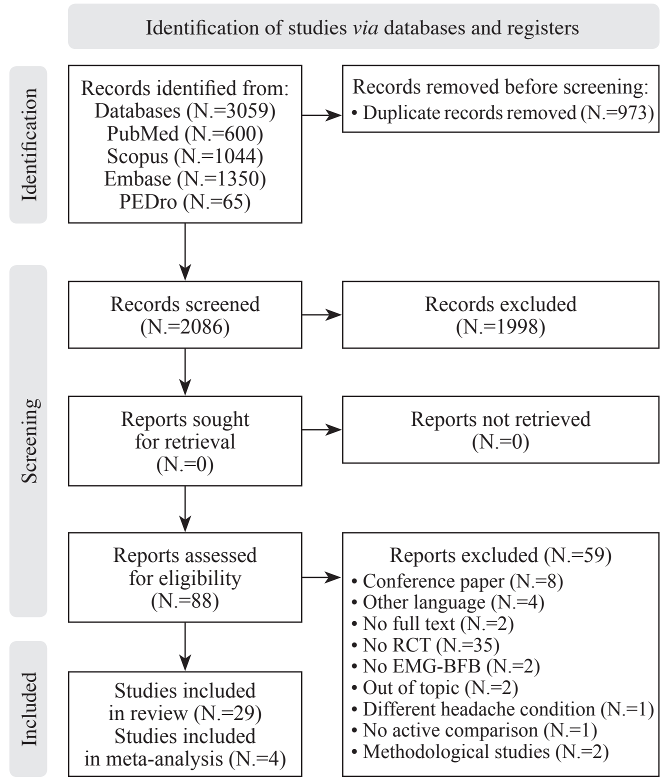


Figure 1.—Flow-chart of search and selection process.

### Population

The included articles consisted of 1342 people suffering from primary headaches, of which 70% were female. Among the participants, 119 (55% male) subjects were paediatrics,[29, 35, 40, 42] with a mean age of 11.07±1.93 years (mean±SD). The mean age of all the patients was 29.12±9.96 years (mean±SD). The sample of the intervention groups was at least 600 while the sample of the control groups was at least 615; in fact, not all studies reported the number of participants in each group. However, none of the included studies reported significant differences in demographic characteristics between groups at baseline. Participants of the studies included in the review suffered from different types of headaches: 56% suffered from tension-type headache, 13% suffered from chronic tension-type headache, 30% suffered from migraine, and 1% suffered from mixed pattern headache. In all studies, post-intervention evaluations were analyzed only for those individuals who finished the training, who were 1216 (91%), except for one study[15] were also the dropped out were analyzed. Overall, 126 participants dropped out and were not analyzed, however none of the included studies reported any treatment-related adverse events. Clear inclusion criteria were reported by nearly all except 6 studies;[17-21] however, the exclusion criteria were clearly defined and reported in only 6 studies.[22-26]

### Intervention

All studies included in the systematic review presented at least one experimental group that used an EMG-BFB for the treatment of headache; among these, five studies[16, 22, 23, 27, 28] used more of an intervention group. All studies performed EMG recording on at least the frontal muscles except one[29] which only did it on the trapezes. Only one study[30] did not specify the site of application of the electrodes. Some studies have used, in addition to the frontal one, another site for electrode placement: right forearm muscle,[22] trapezius,[23, 31, 32] neck muscles,[25, 33] and temporal.[34] Synthetically, in 93% of studies the frontalis muscles have been used like a target for EMG-BFB representing a satisfactory homogeneity about the site of stimulation (Figure 2A).

The EMG-BFB equipment used were all different between the studies; six studies[28,30,34-,37] did not specify which one was used.

Many of the included studies did not report the frequency (in Hz) of EMG data acquisition during the BFB, except for eleven studies.[16, 18, 23, 25-27, 31, 32, 35, 38, 39] The most reported acquisition frequency was between 90-1000 Hz.

The mean duration of the experimental protocols was approximately nine weeks, with a range from two[27] up to 36 weeks.[36] Four studies did not report the duration of the interventions.[21, 24, 27, 31] On average, 13 sessions were performed, about 2 times per week, with a range from ten minutes[29] to 60 minutes.[22, 28] The average duration of the single treatments was ~24 minutes with differences between studies that involve adults[15-34, 36-39, 41, 43] (26.13±8.59 minutes) and pediatric patients[29, 35, 40, 42] (17±10.13 minutes) (Figure 2B).

Some studies[17, 18, 28, 33, 40] have also associated home relaxation work with the experimental treatment, while others[28, 32, 35, 37] associated specific relaxation techniques (see comparison paragraph).

### Comparison

All the included studies used at least one control group to verify the effectiveness of their treatment; seven studies[16, 24, 27, 31, 40-42] also reported a second control group, while four others used three arms study design.[20, 26, 36, 39]

The mean duration of the control protocols was approximately seven weeks, with a range from two[27] up to 36 weeks.[36] Four studies[15, 16, 21, 32] did not report the duration of the intervention. On average, 14 sessions were performed, about three per week, with an average duration of the single training session being about 35 minutes.

Ten studies[18-20, 24, 29, 31, 33-35, 39] use an EMG-BFB as

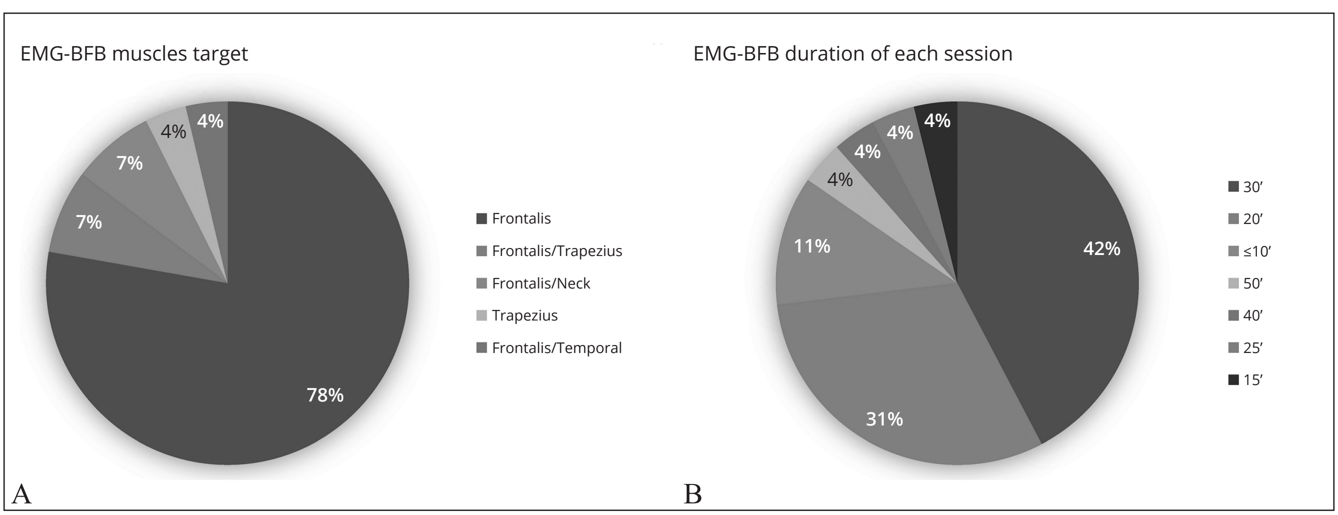


Figure 2.—Distribution rates of EMG-BFB muscles target and EMG-BFB duration of each session across the included studies.

treatment in the control group with the same protocol as the intervention group but using sham treatment. The majority of the studies[23, 27, 30, 31, 36-38, 40-43] performed relaxation techniques, including autogenic training, breathing exercises, Jacobs' techniques, and yoga as a control treatment. Nine studies[16, 18, 27, 32, 36, 40-42] do not perform any active treatment in one of the control groups. One study[22] did not specify the activity performed in the control group.

Two studies[20, 21] used a thermal BFB as a control treatment. Four studies[15, 17, 24, 39] administered a drug (propranolol or diazepam) as a control treatment, including one study[39] also administered a placebo to their third control group. two studies[16, 32] subjected a control group to psychotherapy sessions, while one study[28] to hypnosis sessions.

### Outcome

All the included studies have reported their primary outcomes while only eight studies have declared a secondary one.[15, 18, 19, 22, 24, 29, 35] Although the outcomes were many and heterogeneous, the most reported were headache measures such as frequency, intensity, and duration. Frequency of daily or weekly episodes was used as an outcome from 11 studies;[15, 16, 19, 24, 29, 30, 34, 36, 39, 41, 42] the duration of the episodes in hours per day or week was used as an outcome from eight studies;[15, 16, 19, 24, 28, 36, 40, 42] the intensity of pain during the episodes was used as an outcome from 18 studies, although different scales were used. Five studies[22, 24, 36, 40, 41] used a 11 points scale (from 0 to 10), seven studies[15, 18, 23, 25, 28, 34, 43] used a six-points scale (from 0 to 5), three studies[35, 37, 38] used a five-points scale (from 0 to 4), and two studies[17, 29] used a four-points scale (from 0 to 3). In each of the previous cases the zero value represents the absence of pain while the maximum value represents the strongest headache that can be experienced. One study[39] did not report which was the scale used for the assessment of headache intensity.

Many studies[15, 20-22, 27, 31, 32, 34-36, 39] have reported EMG levels of muscle registration as an outcome measure. Other less reported outcomes were for example: medication/drug intake, headache free-days, physiological measures (*i.e.*, heart rate, temperature).

Most of the selected studies have included a follow-up in their study design except for eight studies.[21, 29, 31-33, 37, 38, 43] The follow-up duration ranged from one-two weeks[16, 41] to one year.[15, 24, 25, 35, 42] The most reported follow-up duration was six months, chosen for nine study design.[15, 17, 24, 25, 27, 30, 35, 36, 40] In nine studies[15, 17-19, 22, 24, 27, 39, 41] that reported statistical improvement after EMG-BFB this effect was maintained in the follow-up evaluation suggesting the effectiveness of duration of results. A summary of the main characteristics of the studies is presented in Supplementary Digital Material 2, Supplementary Table I.

### Risk of bias and confounding factors

A high risk of bias was found in the "Deviations from intended interventions" domain of the RoB tools (Figure 3). This is because only ten of the included studies[18, 22, 24, 25, 29, 31, 33-35, 39] used sham treatment for the control group, so in the other studies the participants and assessors were aware of the treatment they received. In general, the "Randomization process," the "Missing outcome data" and the "Selection of the reported results" domains have a very low risk of bias; in fact, only two studies have shown some concerns. Measurement of outcomes was adequate in all studies except three[19, 23, 27] in which we found some concerns, and except three[30, 32, 37] in which we found a high risk of bias.

The overall risks of bias of the included studies were reached with the help of the decision algorithm provided by Cochrane.[12] The study is judge to be at low risk of bias if all domains are at low risk of bias; the study is judged to raise some concerns if there is at least one domain with this result but no one with an high risk of bias; the study is judged to be at high risk of bias if there is at least one domain with this result or the study is judged to have some concerns for multiple domains in a way that substantially lowers confidence in the result.

Overall, an average moderate/high risk of bias was observed in the selected studies (Figure 3), probably due to the publication date which was prior to 1990 for most of the studies. This may have affected the methodological quality of the included studies with respect to the recent stud-

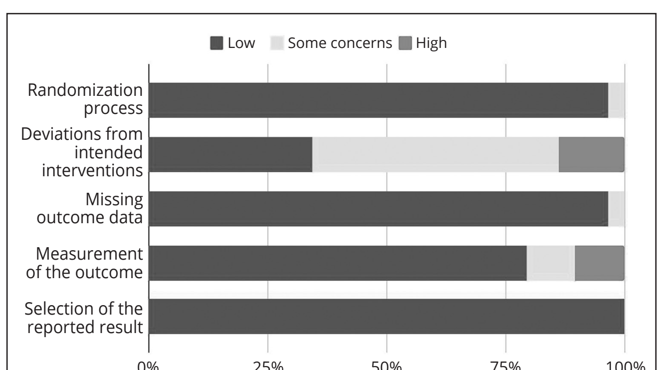


Figure 3.—RoB 2 tools domain frequency of judgements (expressed as a percentage).

ies based on the current RCT guidelines. A table summary of the risk of bias of the studies included is presented in Supplementary Digital Material 3, Supplementary Table II.

About confounding factors in the selected studies there is a high heterogeneity regarding the demographic characteristics (*i.e.*, age) of the study groups and regarding the EMG and protocol (*i.e.*, frequency, duration, device) which cannot be investigated separately due to the small number of studies or the incompleteness of the reported data. These differences can influence the cumulative results. Specifically, studies involving pediatric[29, 35, 40, 42] and adult[15-34, 36-39, 41, 43] subjects were considered for this review and have been merged in the meta-analysis. In the qualitative synthesis, only eleven studies[16, 18, 23, 25-27, 31, 32, 35, 38, 39] reported the frequency used for the EMG-BFB with a high heterogeneity. Likely, the duration and the types of devices is heterogeneous across the studies.

## Meta-analysis

For the present meta-analysis just four studies[15, 24, 29, 40] reported or provided exhaustive data about the headache frequency, intensity, and duration in both the experimental and control groups. In the included studies and for all variables, a decrease in the mean score must be interpreted as an improvement. Concerning this, the effect-size (ES) direction has been corrected and, when greater, is related to a better outcome.

The overall effect size for the headache frequency was 0.17 ([95% CI=-0.06; 0.39], P value=0.14) based on 309 (158/151) patients (Figure 4A),[15, 24, 29, 40] with low heterogeneity ($\chi^2$=1.57, df=3, $I^2$=0, P value 0.66). No potential publication bias was found by the visual assessment of the funnel plot. This was confirmed by Egger's linear regression test (Intercept -0.91, t=-1.11, P value=0.38) and Begg-Mazumdar rank correlation test (Z=-0.68, P value=0.49). The overall effect size for the headache intensity was 0.21 ([95% CI=-0.02; 0.44], P value=0.07) based on 293 (146/147) patients (Figure 4B),[15, 24, 40] with low heterogeneity ($\chi^2$=0.03, df=2, $I^2$=0, P value 0.99). No potential publication bias was found by the visual assessment of the funnel plot. This was confirmed by Egger's linear regression test (Intercept 0.28, t=3.30, P value=0.19) and Begg-Mazumdar Rank Correlation Test (Z=1.57, P value=0.12). The overall effect size for the headache duration was 0.15 ([95% CI=-0.08; 0.37], P value=0.21) based on 293 (146/147) patients (Figure 4C),[15, 24, 40] with low heterogeneity ($\chi^2$=1.23, df=2, $I^2$=0, P value 0.54). A potential publication bias was found by the visual assessment of the funnel plot. This was confirmed by Egger's linear regression test (Intercept 1.95, t=56.09, P value=0.01) and not confirmed by the Begg-Mazumdar Rank Correlation Test (Z=1.57, P value=0.12).

## Discussion

In the present investigation we found a significant decrease in headache symptoms in the EMG-BFB groups with re-

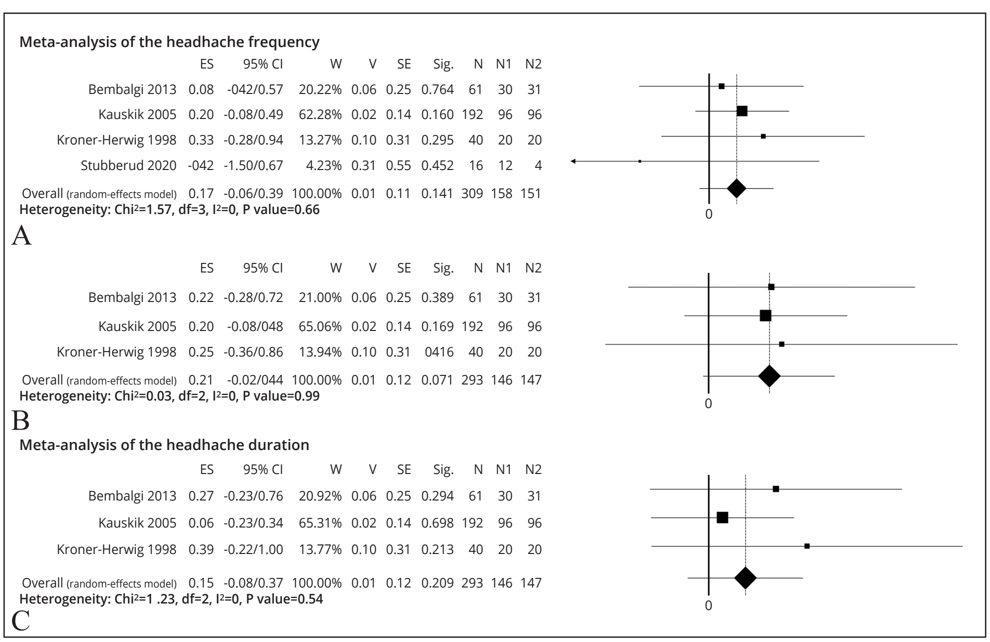


Figure 4.—Forest plots of meta-analysis results for the headache frequency (A), intensity (B) and duration (C) variables.[15, 24, 29, 40]

spect to active or passive control groups in one third of the included studies. Like our findings, a previous systematic review supports the general effectiveness of EMG-BFB when compared to no-treatment, placebo controls and relaxations techniques. The most recurrent target site for EMG-BFB is the frontalis muscles in about 78% of studies included in the synthesis such as shown in the literature[44] (80%) followed by the multiple placement application and neck muscles application.

Our results should be read in the light of previous literature,[44] indicating that various forms of biofeedback are effective for migraine and tension-type headache. Moreover, the therapeutic results achieved with biofeedback are comparable with those obtained with drug therapy and their combination can further improve the results.[6] However, the above cited review also showed that, despite efficacy of EMG-BFB in many patients, it failed to bring significant relief to a sizeable number of headache patients. Also, our review reports some studies obtaining a positive effect of EMG-BFB, but the results of the meta-analysis just approach the statistically significant threshold, without achieving that.

Regarding the durations of the beneficial effects, we observed the maintenance of enhancement in nearly all the studies during the follow-up assessments until one year after EMG-BFB treatment. The durability of improvement has been previously confirmed by Nestoriuc *et al.*, 2008 that reported the persistence of results to several years after EMG-BFB treatment.[44]

Compared to the previous findings, our quantitative synthesis additionally suggests the usefulness of EMG-BFB in the reduction of pain intensity of headache attacks. Differently, no effects have been appreciated on reductions of attacks' durations and frequency.

In recent literature, the role of EMG-BFB in primary headache prevention has been poorly evaluated, although preventive non-pharmacological treatments may represent valid and safe alternatives to conventional drug treatments.[4] In addition to modulating the psychological aspects of patients with chronic disabling pain such as primary headaches, the use of EMG-BFB may contribute to switch-off the pathophysiological mechanisms underlying primary headaches. In migraine patients EMG-BFB may modulate also oxidative stress, suggesting that the effectiveness of this therapeutic approach may be related to vascular and muscular relaxation with a decrease of systemic oxidative stress.[7]

The EMG-BFB could represent an important therapeutic strategy for those patients who need a non-pharmacological approach as well as a reduction in muscle tension and a containment of anxious-depressive comorbidity. The aim of this systematic review and meta-analysis was to investigate whether the use of this preventive approach can be recommended as non-pharmacological treatment in patients with primary headache.

Our results showed that EMG-BFB treatment can reduce the intensity of headache pain but not the frequency and the duration of the headache attacks. This finding may be attributed to discrepancies in case studies and about the methodology for detection of the number and the duration of headache attacks. Furthermore, the preventive treatment with EMG-BFB generally involves a limited number of sessions which may not be sufficient to reduce the number of attacks. In fact, while the intensity of pain is evaluated in a homogeneous way, in almost all the studies with visual-analogue scales, the account of frequency and the duration of attacks is different across the studies, due to the problem to distinguishing between separate attacks and recurrences and because the enrolled subjects are not always precise and compliant with the compilation of the headache diary, often used as a headache monitoring tool. Therefore, the heterogeneity of the protocols can influence the effect size and the variability of results. Efficacy on lowering intensity of pain of headache attacks may depend on the fact that relaxation treatments modulate endogenous opioid system, sympathetic activity, and pain-related brain neuroplasticity.[45] Also, EMG-BFB and relaxation techniques intended to reduce sympathetic activation and engage in mental and physical states of tranquility and well-being in all type of primary headaches.[46, 47]

About the headache-related disability, in this review there is no evidence of effectiveness of the EMG-BFB treatment in the reduction of disability in terms of quality of life and limitation of work and social activities. The lack of standardized protocols for the treatment of headaches with EMG-BFB represents a great challenge to understand the effectiveness of this preventive therapeutic approach and to establish the degree of recommendation for these treatments. The partial clinical utility of the EMG-BFB in primary headache is not new in literature. Halroyd *et al.* affirm that the improvement in tension-type headache outcomes may be a consequence of a combination of non-specific and subjective effects (*i.e.*, how the subject copes to stressors).[48] After all, stress-related vulnerability is associated with both primary headache and psychiatric conditions, as anxious-depressive syndrome. The co-occurrence of these conditions has a great impact on health in primary headache subjects, suggesting a combined action on psychological and somatic symptoms.[49]

Furthermore, EMG-BFB often involves a very low risk of side effects and is also well accepted by subjects affected by primary headache who do not want to follow a drug therapy to avoid possible side effects. Indeed, the American Headache Society recently awarded biofeedback a grade A as a preventative approach to primary headache (*i.e.*, migraine).[50]

### Limitations of the study

There are several limitations to this study. Most of the selected studies have a publication date prior to the year 2000 and this can negatively impact the methodological quality because they are not in line with the current guidelines and make the authors' request for additional data fail. The results of the present systematic review are based on cumulative synthesis that do not consider the differences across the selected studies about demographic characteristics (*i.e.*, age, gender) and EMG-BFB protocol (*i.e.*, frequency, duration, and type of device).

### Future perspective

Further studies are needed to better verify long-term effectiveness of EMG-BFB as treatment in primary headaches. This is because cognitive behavioral treatments could constitute the priority therapeutic choice in subjects who need non-pharmacological therapies or with comorbid psychiatric disorders. Certainly, new randomized and controlled trials are needed to consolidate or refute the results found. Moreover, at the date, more cutting-edge instrumental measures, and biomarkers (*i.e.*, oxidative stress factor) are available as an outcome and can be useful for future deep investigations.

## Conclusions

The EMG-BFB seems able to reduce the intensity of primary headaches attacks without major contraindications, however no difference was observed with respect to frequency and duration between EMG-BFB and controls. Moreover, the literature is obsolete, and the methodological quality is not satisfactory. New studies, with instrumental evaluation, need to verify the fruitfulness of EMG-BFB also on the frequency and duration of attacks. Non-pharmacological preventive therapies are indispensable in clinical practice in primary headaches, particularly in pediatric and in adult patients who cannot undergo drug therapies.

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*Conflicts of interest*

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

*Authors' contributions*

Alex Martino Cinnera and Giovanni Morone contributed equally to this manuscript. Conceptualization: Alex Martino Cinnera, Giovanni Morone and Irene Ciancarelli; methodology and data curation: Alex Martino Cinnera and Alessio Bisirri; data acquisition: Tommaso Lucenti, Mattia Rotundo, Simone Monaci, Claudia Berton, Michela Paoluzzi; data synthesis: Alex Martino Cinnera and Alessio Bisirri; writing-original draft: all authors; writing-review and editing: Alex Martino Cinnera, Giovanni Morone, Irene Ciancarelli and Marco Iosa. All authors contributed to the manuscript and read and approved the final version of the manuscript.

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# SUPPLEMENTARY DIGITAL MATERIAL 1

## Search strategy

**Pubmed**
((("Headache Disorders"[Mesh]) OR "Migraine Disorders"[Mesh] OR "Cluster Headache"[Mesh] OR "Tension-Type Headache"[Mesh]) AND ("Electromyography"[Mesh] OR "Biofeedback, Psychology"[Mesh] OR "EMG")) AND (("1900/01/01"[Date - Publication] : "2023/05/01"[Date - Publication]))

**Scopus**
"Headache Disorders" OR "Migraine Disorders" OR "Cluster Headache" OR "Tension-Type Headache" AND "Biofeedback, Psychology" OR "EMG" AND ( LIMIT-TO ( DOCTYPE , "ar" ) ) AND ( LIMIT-TO ( LANGUAGE , "English" ) )

**PEDro**
“Headache” AND “Migraine” AND “Cluster Headache” AND “Tension-Type Headache”AND “Biofeedback” AND “Electromyography” AND “EMG”

**EmBase**
('headache disorders'/exp OR 'headache disorders' OR 'migraine'/exp OR 'migraine' OR 'tension-type headache'/exp OR 'tension-type headache' OR 'cluster headache'/exp OR 'cluster headache') AND ('biofeedback'/exp OR 'biofeedback' OR 'emg'/exp OR 'emg' OR 'electromyography'/exp OR 'electromyography') AND [embase]/lim NOT ([embase]/lim AND [medline]/lim)

SUPPLEMENTARY DIGITAL MATERIAL 2

Supplementary Table I.—Synoptic table of studies included in the Review.

| **Authors, year** | **Aim of the study** | **Participants**<br>**N**<br>**(gender)**<br>**mean age ± sd/ age range** | **EMG-BFB device; Location and Frequency acquisition (Hz)** | **Intervention protocol**<br>**(Session frequency and duration)** | **Comparison protocol**<br>**(Session frequency and duration)** | **Headache characteristics assessed** | **Outcomes**<br>*Primary*<br>*Secondary* | **Follow-Up**<br>Duration | **Results** |
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| **Fentress et al., 1986** | To assess and compare the therapeutic efficacy of BFB and relaxation response training. | 18<br>(7M, 11F)<br>10.1 ± NR<br><br>IG: 6<br>(NR gender)<br>8-12 years<br><br>CG1: 6<br>(NR gender)<br>8-12 years<br><br>CG2: 6<br>(NR gender)<br>8-12 years | NR;<br><br>Frontalis muscles;<br><br>(NR Hz) | Patients have been performed EMG-BFB, meditative relaxation training and pain behaviour management.<br><br>(7 weekly sessions, followed by 2 bi-weekly sessions, each lasting 1 h, for a total of 15 weeks. They received 8 minutes of biofeedback per session, divided into four-minute trials) | CG1: received instruction in 2 techniques that elicited the relaxation response (progressive muscle relaxation and meditative relaxation) and pain behaviour management.<br><br>CG2: (waiting list) these patients were seen at the beginning of the study to explain the data collection procedures and attended a session in the seventh week. Once the 15-week study period was completed, five of the six patients were randomly assigned to the 2 treatments: 2 to the CG1 and 3 to the IG.<br><br>(7 weekly sessions, followed by 2 bi-weekly sessions, each lasting 1 h, for a total of 15 weeks) | Frequency (n/week);<br><br>Duration (h/week);<br><br>Intensity (1-4);<br><br>Activity per week (duration x frequency) | *Primary:*<br><br>Frequency (n/week);<br><br>Duration (h/week);<br><br>Activity per week (duration x frequency)<br><br>*Secondary:*<br><br>NR | 12 months | Both treatment groups (IG and CG1) were significantly improved at the end of treatment on all measures. Significant differences existed for all three measures of headache frequency, total hours of headache and headache activity. There was no difference between the treatment groups at FU, indicating the parity of treatments with respect to maintenance of effect. |

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| **Kroner-Herwig et al., 1998** | To directly compare the efficacy of progressive relaxation and EMG-biofeedback for children with tension-type and "combined" headache in a RCT design. | 50<br>(60%F, 40% M)<br>10.96 ± 1.93<br>8–14 years<br><br>IG: 20<br>(NR gender)<br>NR age<br><br>CG1: 20<br>(NR gender)<br>NR age<br><br>CG2: 10<br>(NR gender)<br>NR age | SOME Biofeedback 4500;<br><br>Frontalis muscle;<br><br>(NR Hz) | In each BFB session two or three feedback-assisted relaxation trials of 3 min each and two or three self-control trials were conducted in which the children were to relax without the feedback signal. This resulted in a total of 15 min of relaxation practice per session. There was a 1-min intermission between the trials. The children in the BF group were also instructed to practise the relaxation exercises at home.<br><br>(2 weekly sessions for a total of 12 individual sessions of 30 min each) | CG1: exercises started with tensing and relaxing specific muscle groups and went on to whole body relaxation. Breathing exercises were held from the beginning. Relaxation was supported by music.<br><br>CG2: participated in the self-monitoring CG (No treatment).<br><br>(1 weekly session for a total of 6 individual sessions of 1 h each) | Duration;<br><br>Intensity<br>( 0-10);<br><br>Medication<br>(n° of intakes a day);<br><br>Disruptive effects of headache (marking activities that were interrupted or avoided on a list of six categories). | *Primary:*<br>Duration;<br>Intensity<br>( 0-10);<br>Medication<br>(n° of intakes a day);<br>Disruptive effects of headache<br><br>*Secondary:*<br>NR | 6 months | Multivariate analyses of variance on the headache diary data yield no significant main or interaction effects of treatment format, but only a main effect of period, indicating a general efficacy of the treatment conditions. At follow-up the reduction of headache activity is even more prominent. A different evaluative approach points to the superiority of BFB revealing a mean effect size for BFB training that reflects a good to excellent improvement rate. |
| **Stubberud et al., 2020** | To investigate the effect size, safety, and tolerability of a therapist-independent BFB treatment app among adolescents with migraine. | 16<br>(11F 5M)<br><br>IG: 12<br>(10F, 2M)<br>15 ± 2<br>13–18 years<br><br>CG: 4<br>(1F, 3M)<br>14 ± 2<br>12–16 years | Bipolar surface EMG sensor (NeckSensorTM;EXPAIN AS, Oslo, Norway); MIO FuseTM (Mio Global, Physical Enterprises).<br><br>Upper Trapezius<br><br>(NR Hz) | The treatment comprised a self-administered treatment app, including BFB training, instructions for self-delivery, and a headache diary. Participants were instructed that the goal of the BFB sessions was to increase skin temperature and decrease heart rate and muscle tension.<br><br>(2 months daily BFB sessions of 10 min each) | Same protocol but with a sham stimulation.<br><br>(2 months daily BFB sessions of 10 min each) | Frequency<br>(days/month);<br><br>Intensity<br>(0-3);<br><br>Responder rate;<br><br>Abortive drug consumption | *Primary:*<br>Change in the frequency of headache days from baseline to end of treatment<br><br>*Secondary:*<br>responder rate (more than 50% reduction in frequency);<br>change in maximal and average pain intensity (0-3);<br>change in functioning in daily activities (0-3);<br>change in number of days with abortive drug consumption;<br>Adverse Events. | NR | Adherence was poor with 40% of planned BFB sessions completed during weeks 5–8. Within the IG, a not statistically significant reduction in headache frequency was observed at weeks 1–4 and weeks 5–8. The IG experienced a median of one fewer headache days/month versus sham that did not reach significance. |

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| **Bussone et al., 1998** | Not clearly defined. | 30<br>(15F, 15M)<br><br>IG: 20<br>(10F, 10M)<br>11.1 ± 2.6 years<br><br>CG: 10<br>(5F, 5M)<br>13 ± 1.5<br>years | NR;<br><br>Frontalis muscles;<br><br>(100-1000 Hz). | Patients were seated in comfortable recliners and were encouraged to close their eyes to enhance relaxation effects. The first 4 sessions were devoted to progressive muscle relaxation training which focused on relaxation exercises for eight muscle groups (lower arms, upper arms, legs, abdomen, chest, shoulders, eyes, and forehead). EMG-BFB was introduced at the fifth session and this treatment remained the focus for the remaining sessions (6 in all).<br><br>(2 weekly sessions for a total of 10 sessions of 20 min each) | Same protocol but with a sham stimulation.<br><br>(2 weekly sessions for a total of 10 sessions of 20 min each) | Intensity<br>(0-4) | *Primary:*<br>Intensity<br>(0-4);<br>PTI.<br><br>*Secondary:*<br>STAIC;<br>Mean EMG values. | 1 month;<br><br>3 months;<br><br>6 months;<br><br>12 months. | Following treatment, both conditions led to sizable headache reductions (approximately 50%). Over time, children receiving BFB-assisted relaxation continued to improve and were superior to the control condition at a 6- and 12-month follow-up (86% versus 50%). |
| **Abramowitz & Bell, 1985** | To test the belief that muscle contractions are a primary source of tension-type headache. | 24<br>(83%F, 17%M)<br>33.5 ± 10.1<br><br>IG1: 6<br>(NR gender)<br>NR age<br><br>IG2: 6<br>(NR gender)<br>NR age<br><br>CG1: 6<br>(NR gender)<br>NR age<br><br>CG2: 6<br>(NR gender)<br>NR age | Autogen 1700<br><br>Frontalis muscles<br><br>(100-200 Hz) | IG1: Broad-gauged BFB;<br><br>IG2: Broad-gauged BFB plus brief eclectic psychotherapy.<br><br>(2 weekly session for a total of 12 sessions in 6 weeks, of 30 min each) | CG1: Brief eclectic psychotherapy;<br><br>(2 weekly session for a total of 12 sessions in 6 weeks, of 30 min each)<br><br>CG2: waiting-list control (No active treatment). | Duration<br>(h/week);<br><br>Frequency<br>(n/week). | *Primary:*<br><br>Headache frequency<br>(n/week);<br><br>Headache duration<br>(h/week);<br><br>*Secondary:*<br><br>*NR* | 2 weeks | EMG level was found to be associated with both headache-specific and more global symptoms following BFB training. However, the level of pre-treatment relationship between EMG level and headache symptoms was weak, and the amount of reduction in EMG activity over the course of BFB did not explain improvement. In addition, although the voluntary control over muscle spasming evidenced by lowered |

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| | | | | | | | | | EMG readings appeared to enhance patients' post-treatment level of self-control, this cognitive process variable also could not account for outcome variance. |
| **Andrasyk & Holroyd, 1980** | To evaluate the treatment specificity of learned control of frontal EMG activity in the BFB treatment of tension headache. | 39<br>(33F, 6M)<br>19.7 ± NR<br><br>IG1: 10<br>(NR gender) NR age<br><br>IG2: 9<br>(NR gender) NR age<br><br>IG3: 10<br>(NR gender) NR age<br><br>CG: 10<br>(NR gender) NR age | Cyborg BL 933<br><br>IG1:<br>frontal<br>IG2: right forearm muscle<br><br>IG3: inverted frontal feedback<br><br>(NR Hz) | At each session, subjects received 20 minutes of BFB, followed by a 10-minute no-feedback (self-control) period. During treatment, subjects were seated in heavily padded, high-back chairs with broad arm supports; therapists were seated behind the subjects.<br><br>(1 hour session for 2 sessions/week for 7 total sessions) | Subjects provided daily ratings of their headache severity. Subjects met with a research assistant on a weekly basis. These meetings lasted approximately 30 minutes and were held to ensure that headache recording was being performed in a reliable and accurate manner.<br><br>(30 min sessions for 1 a week) | Headache activity (intensity and duration);<br><br>Frequency (n/week);<br><br>Elevated duration (n hours for each headaches achieving a peak intensity);<br><br>Total duration;<br><br>Peak intensity (the highest intensity rating for a given week);<br><br>Mean intensity. | *Primary:*<br><br>EMG activity;<br><br>daily recordings of headache severity and medication intake on headache data cards;<br><br>Headache intensity (0-10).<br><br>*Secondary*<br><br>Treatment credibility. | 6 weeks | Analysis of EMG data revealed that frontal muscle tension levels varied during both training and self-control periods. Irrespective of this, the three BFB procedures produced similar effects on headache at both post-treatment and 6-week follow-up assessments. All three BFB groups were found to be significantly improved relative to the recording group on most measures; no differences were found between the three BFB groups. |
| **Arena et al., 1995** | To evaluate the differential effects of three psychophysiological treatments for tension headache: frontal/upper trapezius EMG-BFB training, and a standard progressive muscle relaxation therapy regimen. | 26<br>(21F, 5M)<br>44.5 ± NR<br><br>IG1: 8<br>(5F, 3M) 39.5±12.9 years<br><br>IG2: 10<br>(9F, 1M) 37.2±8.7 years<br><br>CG: 8<br>(7F, 1M) 44,9±13.8 years | J&J EMG module M-501<br><br>IG1:<br>Frontalis muscles<br><br>IG2:<br>Upper trapezius<br><br>(90-200 Hz) | Each BFB training session consisted of the following sequence: (1) collection of headache diary data and check on home practice; (2) connection of sensors/adaptation period; (3) in-session baseline; (4) self-control phase, in which subjects attempt to decrease their muscle tension | A modified version of progressive muscle relaxation therapy<br><br>(7 total sessions for 8 weeks) | Headache Intensity (0-6);<br><br>Headache improvement: (number of headache-free days, peak headache activity, and medication index). | *Primary:*<br><br>Headache diary in which subjects were asked to note their degree of headache activity using a six-point scale four times a day.<br><br>*Secondary:*<br><br>Headache improvement. | 1 months;<br><br>3 months. | Post-treatment assessment at 3 months following cessation of treatment revealed clinically significant decreases in overall headache activity in 50% of subjects in the frontal biofeedback group, 100% in the trapezius biofeedback group, and 37.5% in the relaxation therapy group. Chi-squared |

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| | | | | without feedback; (5) feedback training; (6) a second self-control phase; (7) removal of sensors and rescheduling. Trapezius EMG was recorded bilaterally; feedback was given from the side which had the highest EMG levels<br><br>(12 total sessions of 50 min for 9 weeks) | | | | | analyses indicated that the IG2 was more effective in obtaining significant clinical improvement than the IG1 and CG (which did not differ from each other). The three treatments did not differ on secondary measures of headache improvement. |
| **Bembalgi & Naik, 2013** | To compare the efficacy of EMG-BFB and galvanic skin resistance BFB in patients with tension type headache. | 91<br>(59 F, 32 M)<br>41.5 ± NR<br>18-65 years<br><br>IG: 30<br>(NR gender) 37.4 ± 10.9 years<br><br>CG1: 30<br>(NR gender) 35.6 ± 8.6 years<br><br>CG2: 31<br>(NR gender) 37.3 ± 10.5 years | EMG-BFB was provided by an EMG-IR Retrainer (Chattanooga Group Inc., Hixson, TN, USA)<br><br>Frontalis muscles<br><br>(NR Hz) | All subjects were instructed to reduce the intensity and frequency of the sound as well as reduce the number of glowing bars and the digital numerical display in the case of the EMG-BF group (IG); and<br><br>(15 sessions of 30 min each) | CG1: All subjects were instructed to increase the number of glowing green bars along with digital numbers and avoid getting the red bars to glow in the case of the CG (Galvanic-skin resistance)<br><br>(15 sessions of 30 min each)<br><br>CG2: received only medication prescribed by their physician. | Headache frequency (n/week);<br><br>Headache duration (h/week);<br><br>Headache intensity (0-10). | *Primary:*<br><br>Headache frequency (n/week);<br><br>Headache duration (h/week);<br><br>Headache intensity (0-10);<br><br>SF-36 scores.<br><br>*Secondary:*<br><br>NR | 1 month;<br><br>6 months;<br><br>12 months. | There was a significant difference in frequency and duration of headache in the IG and the CG1, whereas the CG2 showed significant differences in intensity and duration. Significant improvement was seen only in total SF-36 scores after 1 year in the IG and CG2. A significant drop in analgesic usage was seen in all groups at 1 year. |
| **Bruhn et al., 1979** | To compare the EMG feedback method against other therapies in a group of patients with chronic, incapacitating muscle contraction headache resistant to traditional treatment. | 23<br>(14F, 9M)<br>35.1 ± NR<br><br>IG: 13<br>(NR gender) NR age<br><br>CG: 10<br>(NR gender) NR age | Commercial EMG feedback equipment (Biotens, Biometer, Odense, Denmark).<br><br>Frontalis muscles<br><br>(NR Hz) | The patients were urged to do "whatever would reduce the pitch of the feedback signal." No supplementary instructions about relaxation were given, but patients were asked to use the acquired skills during 30 minutes of home practice a day. Initial | Physical therapy and drugs, alone or in combination.<br><br>(NR frequency and duration) | Headache intensity (0-3);<br><br>Headache duration (3 times/day). | *Primary:*<br><br>Headache intensity (0-3);<br><br>Headache duration (3 times/day).<br><br>Drug intake units (daily)<br><br>*Secondary:* | 1 month;<br><br>3 months;<br><br>6 months. | Headache intensity and severity as well as drug intake were reduced in the IG as opposed to no improvement in the CG. The positive treatment effect in the IG persisted through a three-month follow-up period. |

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| | | | | EMG values were recorded at the beginning of each training session to check if the patient was able to reduce tension without feedback.<br><br>(16 sessions, twice weekly of 20 min each for 4 weeks) | | | NR | | |
| **Budzinsky et al., 1973** | To prove that the EMG feedback training is effective in reducing the frequency and severity of tension headaches. | 18<br>(16F, 2M)<br>36 ± NR<br>22-44 years<br><br>IG: 6<br>(NR gender)<br>NR age<br><br>CG1: 6<br>(NR gender)<br>NR age<br><br>CG2: 6<br>(NR gender)<br>NR age | The "BIFS" EMG feedback system (Bio-Feedback Systems, Inc., Boulder, Colorado<br><br>Frontalis muscle;<br><br>(120-1000 Hz) | IG1<br>EMG BFB training. + daily practice outside the laboratory: patients in IG1 were told to practise relaxation outside of the laboratory for two 15-20 minute periods every day.<br><br>(2 weekly sessions for a total of 16 sessions) | CG1<br>Patients also received the "feedback" except that it was tape recorded from the IG (the "pseudo feedback" condition). Thus, they received non contingent feedback. Moreover, patients were told to practice relaxation outside of the laboratory for two 15-20 minute periods every day.<br><br>CG2<br>no training<br><br>(2 weekly sessions for a total of 16 sessions) | Headache intensity (0-5);<br><br>Headache frequency. | *Primary:*<br><br>Daily charting of their headache activity;<br><br>*Secondary:*<br><br>Questionnaire designed to assess evidence of symptom substitution and levels of medication usage | 3 months. | A significant reduction in muscle contraction headache activity was observed in patients trained in the relaxation of the forehead musculature through EMG-BFB. CG1 and CG2 failed to show significant reductions. A three-month follow-up questionnaire revealed a greatly decreased medication usage in the IG. |
| **Carrobles et al., 1981** | Main aims: (1) to investigate the independent contribution of BFB training; (2) to investigate the effects of including shaping procedures upon results; (3) to investigate the value of using a variety of conditions in the same laboratory situation in facilitating the | 9<br>(NR gender)<br>38 ± NR<br><br>25-60 years<br><br>IG: 5<br>(NR gender)<br>NR age<br><br>CG: 4<br>(NR gender)<br>NR age | EMG-BF: Farrall Instruments Inc. Biofeedback Integrated System, model PM-9. The apparatus is equipped with both audio and visual feedback displays.<br><br>Frontalis muscle;<br><br>(NR Hz) | At the beginning subjects received continuous auditory and visual feedback, with the task of reducing feedback intensity from the apparatus. At the same time they were instructed to discover the feelings and sensations associated with such changes. | When the subject arrived at the consulting-room they were asked to sit down in an armchair in front of the therapist, and a discussion took place of the matters noted on the subject's record card, emphasis being given to the activities the subject | Headache frequency;<br><br>Headache duration;<br><br>Headache onset; | *Primary:*<br><br>Headache frequency;<br><br>Headache duration;<br><br>Headache onset;<br><br>Medication taken<br><br>*Secondary:*<br><br>Neuroticism and extraversion (EPI) | 4 months;<br><br>10 months. | Following treatment, results indicated that BFB was significantly superior to the control condition in reducing headache. Subjects in the IG achieved a high degree of control over EMG responses under different stress conditions. Progress was maintained at 10-months follow-up. |

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| | transfer of training to everyday life situations. | | | Once subjects had achieved muscle tension control they moved to a binary-feedback procedure consisting of a light showing whenever the subjects' muscle tension exceeded the level chosen as the criterion on each test occasion. Following this, subjects were given feedback in the form of the experimenter saying yes/no, every five minutes, depending on whether subjects achieved or did not achieve the criterion set on any occasion. A final phase of EMG response 'shaping and generalisation training' was given. During this phase principles of learning such as 'shaping' and 'generalisation' were introduced to secure transfer of training to subjects' life situations.<br><br>(A total of 8 sessions of 30 min each, twice weekly for 4 weeks) | was engaged in when the headache occurred. Frontalis EMG tension was measured at the end of each session, but no feedback was given (Sham BFB). Subjects were given 'high expectations of cure' by their being informed that they would be inevitably and finally cured. Subjects remained seated for the whole session, and other experimental setting conditions were also constant.<br><br>(A total of 8 sessions of 30 min each, twice weekly for 4 weeks) | | | | |
| **Cohen et al., 1980** | To provide a controlled comparison of four modes of BFB training for migraine headaches. | 34<br>(82%F)<br>42 ± NR<br>23-60 years<br><br>IG: 9<br>(NR gender)<br>NR age<br><br>CG1: 9<br>(NR gender) | Model 401C Electromyogram Biofeedback Technology Inc. portable units<br><br>Frontalis muscle;<br><br>(NR Hz) | Frontalis EMG:<br>The person was seated in a comfortable chair. Following attachment of electrodes and transducers, the patient was asked to speak into a tape recorder for 5 min about anything he /she | CG1: Same protocol as experimental group but the alpha group received a tone-off, tone-on signal denoting the presence or absence of alpha above threshold.<br><br>CG2: Temperature trainers received a | Headache frequency (n/week);<br><br>Headache intensity (0-4);<br><br>Disability;<br>(0-4)<br><br>Length of headache. | *Primary:*<br><br>Forehead and finger temperatures, frontalis EMG, alpha activity in the EEG, skin conductance, heart rate, and finger pulse amplitude | 8 months. | The results of analyses on the number of headaches per week, average length, disability, and intensity produced no group differences on any of these variables. Headaches per week was the only measure of headache activity |

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| | | NR age<br><br>CG2: 8<br>(NR gender)<br>NR age<br><br>CG3: 8<br>(NR gender)<br>NR age | | cared to. A 10-min rest period ensued, which was followed by a 20-min training session. At the completion of training another 5-min verbal sample was obtained. For all patients, feedback consisted of a tone delivered through a loudspeaker placed near the person's head. The EMG group received a tone that changed pitch in direct proportion to system fluctuations.<br><br>(24 total sessions of 35 min each, 3 sessions/week for 8 weeks) | tone that changed pitch in direct proportion to system fluctuations, they received differential temperature feedback from the finger and forehead.<br><br>CG3: Vasomotor trainers received a tone that changed pitch in direct proportion to system fluctuations<br><br>(24 total sessions of 35 min each, 3 sessions/week for 8 weeks) | | *Secondary:*<br><br>NR | | that changed over the course of the study. For all training conditions, it showed about a 20% reduction from pretraining to the fourth post training block. |
| **Cram et al., 1980** | To examine potential treatment components by utilising three different procedures while comparing these to a typical EMG-induced relaxation procedure. | 32<br>(25F, 7M)<br>31.8 ± 10.2 18-64 years<br><br>IG1: 8<br>(NR gender)<br>NR age<br><br>IG2: 8<br>(NR gender) NR age<br><br>CG1: 8<br>(NR gender)<br>NR age<br><br>CG2: 8<br>(NR gender) NR age | J & J Enterprises, M-55<br><br>Frontalis muscle;<br><br>(100 and 200 Hz) | IG1: EMG-induced relaxation. It was comprised of four treatment components: (1) contingent analogue audio feedback from the frontalis muscle; (2) instructions to lower the tone and EMG activity; (3) attending to an audio signal; (4) charting of headache activity and associated situations.<br><br>IG2: EMG stability training.This procedure contained all of the components of the first group, with the exception of the instructions to lower the tone and EMG | CG1: Meditation on tone. The analogue tone to which the subject attended was yoked from another subject, and they were instructed in a more general relaxation technique using the basic elements of the Relaxation Response.<br><br>(Two weekly sessions of 30 min each for a total of 3 hours of treatment)<br><br>CG2: Chart headaches only. This procedure employed only one treatment component: The charting of headache activity and notation of situations, thoughts, and feelings | Headache frequency;<br><br>Headache severity. | *Primary:*<br><br>Diary of headache activity; notations of any situations, thought, or feeling states associated with changes in the intensity of their headache activity<br><br>*Secondary:*<br><br>NR | 6 months. | Only IG1 and IG2 showed a significant reduction in headache activity. At the 6-month follow-up, the IG1 had begun to show a return of headache activity, while the IG2 evidenced a continued reduction in headache activity. |

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| | | | | activity. Instead, this group was asked to stabilise their EMG activity at their basal levels. For this group, the contingent analogue audio feedback was turned "off" whenever the subjects' on-going EMG activity exceeded or fell below ± 10% of the mean basal EMG activity levels established during the rest periods of their three prebase line sessions. They were instructed to keep the tone on as much as possible.<br><br>(Two weekly sessions of 30 min each for a total of 3 hours of treatment) | associated with changes in headache intensity. During their weekly sessions, situational themes, if present, were high-lighted without recommending alternative methods for coping with these situations.<br><br>(1 h session per week for a total of 3 hours of treatment) | | | | |
| **Gada et al., 1984** | To find out efficacy of frontalis EMG-BFB therapy, deep muscular relaxation therapy and compare the efficacy of both in cases of tension headache | 58<br>(19M,39F)<br>NR age<br><br>IG: 30<br>(11M, 19F)<br>35.2 ± NR years<br><br>CG: 28<br>(8M, 20F)<br>36.4 ± NR years | EMG J 33 muscle trainer of Cyborg Corporation (U.S.A.)<br><br>Frontalis muscles;<br><br>(NR Hz) | Auditory feedback was provided by converting the averaged frontal EMG signal into a tone that varied in pitch depending upon the input voltage. Feedback was provided in a binary fashion using a voltage level detector which turned the feedback signal off when the muscle-tension level decreased to a predetermined level. Subjects were instructed to keep their eyes closed throughout the | The patients in this group were given deep relaxation therapy by Jacobson relaxation technique. The patient was made to lie comfortably on a couch. The patients were then taught progressive muscular relaxation.<br><br>(30 min session twice a week for 10 weeks) | Number of headache-free days per week;<br><br>Peak headache intensity for each week;<br><br>Headache intensity (0-5);<br><br>Average daily headache activity score per week. | *Primary:*<br><br>Number of headache-free days per week;<br><br>Peak headache intensity for each week;<br><br>Headache intensity (0-5);<br><br>Average daily headache activity score per week.<br><br>*Secondary:*<br><br>NR | NR | By the end of 10 weeks the average daily headache score in the IG had dropped from 5.5 to 2.4 and in the CG from 5.2 to 2.5. There was no significant difference between the two groups on average daily headache scores. |

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| | | | | session.<br><br>(30 min session twice a week for 10 weeks) | | | | | |
| **Gray et al., 1980** | To look more systematically at the relationship between electrode site and outcome in a group of tension headache subjects. | 15<br>(9M, 6F)<br>33.8 ± 14.48<br>20-70 years<br><br>IG: NR<br>(NR gender)<br>NR age<br><br>CG1: NR<br>(NR gender)<br>NR age<br><br>CG2: NR<br>(NR gender)<br>NR age | Two portable battery-operated Biofeedback Systems Ltd EMG 90 machines;<br><br>Frontalis muscles; Trapezius.<br><br>(100-1000 Hz) | IG: Direct feedback. Electrodes were placed on the frontalis muscles and on the trapezius muscles; feedback was provided only from whichever of the two sources corresponded to the perceived location of the pain, but EMG recordings were taken from both sites. Subjects in this group, on the first treatment session, received short instruction in relaxation techniques.<br><br>(6 sessions of 20 min each, once a week for 6 weeks) | CG1: Indirect feedback. The electrodes were placed as in the IG. The feedback however was provided from the source not corresponding to the perceived location of the pain, and EMG recordings were again made from both sites.<br><br>(6 sessions of 20 min each, once a week for 6 weeks)<br><br>CG2: Relaxation only. The subjects in this group heard taped relaxation instructions.<br><br>(15-20 min each day)<br>. | Headache frequency;<br><br>Headache duration;<br><br>Headache intensity (0-4);<br><br>Medication taken. | *Primary:*<br><br>Muscle tension; Headache activity (frequency, duration and intensity);<br><br>*Secondary:*<br><br>NR | NR | No significant differences were found between base-line and post-treatment EMG levels. for any of the groups; however, some significant reductions in levels were obtained within sessions. EMG levels recorded during headache attacks did not differ significantly from levels recorded during base-line. Frequency and intensity of headaches were significantly reduced. particularly in the CG2. At follow-up this improvement was maintained for subjects with forehead pain. but differences between the groups had disappeared. |
| **Hart & Chichanski, 1981** | To compare EMG BFB from the frontal area with EMG biofeedback from the neck in the treatment of chronic muscle contraction headache. | 20<br>(8M, 12F)<br>NR age<br><br>IG: 10<br>(4M, 6F)<br>32.6 ± NR<br>18-60 years<br><br>CG: 10<br>(4M, 6F)<br>33.6 ± NR<br>18-60 years | Surface EMG recordings were made using Beckman Ag/AgC1 Integrated; EMG was obtained and feedback provided by a Med-1000 Programmable Physiological System.electrodes and Beckman electrolyte. The amplified and integrated EMG output was recorded on a Beckman Type RP Dynograph. | IG: Frontalis EMG-BFB.<br><br>Each session consisted of a 5-minute pretraining baseline, 20 minutes of feedback, and an additional 5-minute baseline period. Subjects were asked to practise twice a day for 15-20 minutes each time.<br><br>(15 total sessions, | CG: Neck EMG BFB. Same IG protocol but with different EMG location.<br><br>(15 total sessions, once a week, of 30 min each) | Headache intensity (0-5);<br><br>Medication consumption. | *Primary:*<br><br>Headache intensity (0-5);<br><br>Medication consumption<br><br>*Secondary:*<br><br>NR | 6 months;<br><br>12 months. | Both groups evidenced significant decreases in reported headache activity, with the CG also significantly reducing medication consumption. An analysis of EMG changes suggested that subjects were able to produce large within-session changes in EMG activity during initial sessions, with the |

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| | | | Frontalis muscles;<br>Neck Muscles.<br><br>(90-1000 Hz) | once a week, of 30 min each) | | | | | major effect of additional training being an increase in speed with which these changes occurred. In neither group, however, did changes in EMG activity correspond closely to changes in reported headache activity. |
| **Hart et al., 1984** | Not clearly defined. | 102<br>(61F, 41M)<br>38.9 ± 13.13<br>17-60 years<br><br>IG: 70<br>(NR gender) NR age<br><br>CG: 32<br>(NR gender) NR age | Coulbourn Instruments;<br><br>Frontalis muscle;<br><br>(90-100Hz) | BFB consisted of a series of tones that varied in pitch as a function of the amount of integrated EMG activity. In addition, when EMG activity fell below a predetermined target level, the signal was turned off. The nature of the task and the relationship between the signal and muscle activity was explained to the patient prior to the first training session and was repeated and clarified whenever necessary.<br><br>(12 total sessions of 35 each, once a week for 12 weeks)<br><br>Patients were asked to adopt a regular program of home practice.<br><br>(one or two 15-20 mi sessions per day) | The relaxation training procedure employed was a series of tapes that had elements of a variety of relaxation strategies including progressive muscle relaxation, imagery, and suggestion. The following tapes from the series were used in this study: Tense-Slow-Relax (2 sessions), Differential Relaxation (2 sessions), Limb Heaviness (2 sessions), and Forehead and Facial Relaxation (4 sessions).<br><br>(12 total sessions of 35 each, once a week for 12 weeks)<br><br>Patients were asked to adopt a regular program of home practice.<br><br>(one or two 15-20 mi sessions per day) | Headache intensity (0-5) | *Primary:*<br><br>Headache intensity (0-5);<br>Percent improvement (the difference between the mean during baseline and the mean for the last 2 weeks divided by the baseline mean)<br><br>*Secondary:*<br><br>NR | NR | The analysis demonstrated that relaxation training was significantly more effective than BFB and that mixed headache patients improved significantly less than either migraine or muscle-contraction headache patients, and that there is a significant interaction between treatment type (relaxation vs. BFB) and cognitive structure. |

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| **Haynes et al., 1975** | To assess the comparative effectiveness of relaxation instructions and frontalis EMG-BFB in the treatment of tension headaches. | 21<br>(14 F, 7M)<br>20.9 ± NR<br><br>IG: 8<br>(NR gender)<br>NR age<br><br>CG1: 8<br>(NR gender)<br>NR age<br><br>CG2: 5<br>(NR gender)<br>NR age | PA-2 Bioelectric Information Feedback System;<br><br>Frontalis muscles;<br><br>(NR Hz) | Baseline EMG activity was then assessed for 9.8 min prior to any experimental instructions. Subjects were told to become as relaxed as possible and that they would hear a tone to assist them in relaxing. The pitch of the tone varied directly with the relative level of EMG activity. At the end of the experimental phase, each subject received a taped message that he was learning how to relax and that he should employ what he was learning to prevent or terminate his headaches.<br><br>(6 total sessions of 30 min each, twice weekly for 3 weeks) | Same protocol as intervention group but subjects in the group: CG1 (the relaxation instructions group) received taped relaxation instructions. Subjects in the group: CG2: (no-treatment group) were told to become as relaxed as possible but received no further intervention procedure.<br><br>(6 total sessions of 30 min each, twice weekly for 3 weeks) | Headache intensity (0-10);<br><br>Headache frequency; | *Primary:*<br><br>Headache intensity (0-10);<br><br>Headache frequency;<br><br>*Secondary:*<br><br>NR | 1 week;<br><br>5 months;<br><br>7 months. | The IG and the CG1 resulted in significant decreases in reported headache activity. Both procedures were significantly more effective than the CG2 procedure but did not differ significantly from each other in effectiveness. The effectiveness of the two procedures was maintained at follow-up. Frontalis EMG levels were higher during sessions in which a headache was reported than in sessions when no headache was reported. The importance of individual differences is emphasised. |
| **Huszinski et al., 1984** | To determine if chronic muscle contraction headache subjects who received training in muscle discrimination during a headache treatment program that included the standard application of behavioral procedures would be able to relieve muscle activity more effectively than those subjects who received only the conventional program. | 30<br>(18F, 12M)<br>37 ± NR<br>21-60 years<br><br>IG: 16<br>(NR gender)<br>21-60 years<br><br>CG: 14<br>(NR gender)<br>21-60 years | Autogenic 1500 electromyogram units;<br><br>Frontalis muscles;<br><br>Neck muscles.<br><br>(NR Hz) | Frontalis EMG biofeedback and also cervical EMG feedback with relaxation procedures and home relaxation practice was performed.. Subjects received the increased or intensified muscle discrimination training, along with the standard headache program alone.<br><br>(10 total sessions of 50 min each, once a week for 10 weeks) | The groups differed in their treatment experiences in only one respect: IG subjects received the increased or intensified muscle discrimination training, along with the standard headache program alone.<br><br>(10 total sessions of 50 min each, once a week for 10 weeks)<br><br>All subjects were expected to practise relaxation of musculature at home. | NR | *Primary:*<br><br>Muscle discrimination;<br>contraction headache;<br>muscle contraction activity.<br><br>*Secondary:*<br><br>NR | NR | Results indicated that both groups markedly improved. Although the amount of change between the two groups was not statistically significant, the direction of change improved for the experimental group who received the increased, intensified muscle discrimination training. |

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| | | | | All subjects were expected to practise relaxation of musculature at home.<br><br>(twice a day for no less than 30 minutes each period) | (twice a day for no less than 30 minutes each period) | | | | |
| **Kaushik et al., 2005** | To evaluate utility of BFB assisted diaphragmatic breathing and systematic relaxation in migraine and to compare their efficacy with propranolol in long term prophylaxis of migraine. | 192<br>(132 F, 60M)<br>NR age<br><br>IG: 96<br>(30M, 66F)<br>NR age<br><br>CG: 96<br>(30M, 66F)<br>NR age | BFB apparatus, manufactured by J&J Engineering (Poulsbo, Washington, USA);<br><br>Frontalis muscles;<br><br>(NR Hz) | IG was subjected to EMG and temperature BFB assisted diaphragmatic breathing and systematic relaxation (10 guided sessions) accompanied by home practice of diaphragmatic breathing and systematic relaxation for 6 months which was gradually stopped over next 1 month.<br><br>(10 total sessions, once a week for 10 weeks)<br><br>Home practice: 10 min thrice daily before meals. | CG was started on tablet propranolol 80 mg/day for 6 months followed by gradual tapering of propranolol over 1 month period.<br><br>(80 mg/day for 6 months) | Headache frequency;<br><br>Headache intensity; (0-10)<br><br>Headache duration;<br><br>Number of vomiting. | *Primary:*<br><br>Resurgence rate during post-treatment observation (Resurgence was defined as a 50% or greater increase in headache unit index.)<br><br>*Secondary:*<br><br>Change in frequency, intensity and duration of headache, number of vomiting, measure of change in peripheral temperature and frontalis EMG potentials and patient’s own assessment of well being after 6 months of treatment. | 6 months;<br><br>12 months. | Significant clinical response was seen with biofeedback in 66.66% and with propranolol in 64.58% of patients. Frequency, intensity, duration of attacks and number of vomiting episodes were significantly reduced in both the groups at 6 months, but inter-group differences were statistically insignificant. During 1-year post-treatment period, significantly lesser resurgence of migraine was seen in IGas whole (9.37%) and in biofeedback responders in IG (9.37%) in comparison to resurgence of migraine in CG as whole (38.54%) and in propranolol responders in CG (53.22%) respectively. |
| **Lacroix & Corbett, 1990** | To provide a direct test of the classic etiological account of tension-type headaches, that these stem from elevated levels of muscle | 28<br>(28F)<br>24 ± NR<br><br>IG: NR<br>(NR gender)<br>NR age | An Autogen HT-1 recorded EMG;<br><br>Frontalis muscles;<br><br>(NR Hz) | Subjects in the EMG Target groups were instructed to try to maintain the needle on the EMG display between 9 and 12 pV. Following a 5-min | Temperature Target groups were instructed to try to maintain peripheral temperature above 35°C.Room temperature was | Headache intensity (0-6);<br><br>Other symptoms. | *Primary:*<br><br>Target conditions (EMG or temperature);<br><br>Expectation (either of | NR | Results showed that subjects were successful in complying with their assigned tasks. However, there were no main effects of |

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| | tension. | CG: NR<br>(NR gender)<br>NR age | | adaptation period, the experimental session comprised a 3-min baseline, 40 mm of the BFB-assisted EMG , and a final 3 min of recovery. | maintained at 19 o C. Following a 5-min adaptation period, the experimental session comprised a 3-min baseline, 40 mm of the biofeedback-assisted EMG , and a final 3 min of recovery. | | a headache or of some unspecified discomfort);<br><br>Time interval.<br><br>*Secondary:*<br><br>NR | | Target response or Expectation and no interactions of these factors with respect to headache or any other symptom. |
| **Lake et al., 1979** | To address the following question: is digit temperature BFB alone or in combination with RET more effective in the management of migraine than EMG-BFB or the self-monitoring of headache activity? | 24<br>(19F, 5M)<br>30.5 ± NR<br><br>IG: 6<br>(NR gender, NR age)<br><br>CG1:6<br>(NR gender)<br>NR age<br><br>CG2: 6<br>(NR gender)<br>NR age<br><br>CG3: 6<br>(NR gender)<br>NR age | EMG recordings were obtained from quarter inch diameter AgAgCl Narco Biosystems recessed electrodes (710-0037);<br><br>Frontalis muscles;<br><br>(90-1000 Hz) | Subjects were provided with a repetitive mental device ("RELAX"), and instructions on how to achieve a "passive attitude". EMG levels were manually recorded from all subjects at 60-sec intervals throughout each session.<br><br>(30 min sessions twice per week for 4 weeks) | CG1: Self-monitoring subjects recorded headache activity for at least five months, corresponding to "baseline treatment".<br><br>CG2 and CG3: Subjects were provided with a repetitive mental device ("my hands are warm") and instructions on how to achieve a "passive attitude". Finger temperature levels were manually recorded from all subjects at 60-sec intervals throughout each session.<br><br>(30 min sessions twice per week for 4 weeks) | ;<br><br>Headache duration (h/day);<br><br>Past medical; headache history. | *Primary:*<br><br>Hours of daily headache activity rated "very severe" or “painful”;<br><br>Total hours of daily headache activity;<br><br>% of days in the experimental period with any reported headache activity.<br><br>*Secondary:*<br><br>NR | 3 months. | Digit temperature BFB alone or in combination with RET did not prove to be more effective in the management of migraine than EMG biofeedback training or self-monitoring of headache activity. In some analyses, the three biofeedback groups were more effective than self-monitoring alone, but not different from each other. |
| **Paiva et al., 1981** | To try to shed some light on these controversial points in a well-controlled design. For that, the definition of TH of the International Ad Hoc Committee and Classification of | 36<br>(27F, 9M)<br>37.5 ± NR<br><br>IG: 8<br>(NR gender)<br>NR age | Myotron 220 (Enting Instruments and Systems);<br><br>Frontalis muscles;<br><br>(100-1000 Hz) | IG performed frontalis EMG-BFB: they were asked to relax and try to decrease the frequency of the clicks which they heard through the headphones. | CG1: performed frontalis E(sham) MG-BFB: they were asked to relax and try to decrease the frequency of the clicks which they heard through the headphones. | Headache intensity;<br><br>Headache frequency; | *Primary:*<br><br>Headache intensity;<br><br>Headache frequency;<br><br>Effects of treatment on the resting EMG values. | 4 weeks. | In both true conditions, BFB and diazepam, treatment effects differentiated from placebo groups; with diazepam the strongest results upon headache and frontalis EMG were observed |

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| | Headache is strictly relied upon; a double-blind trial is set for BF false and true, and, equally in a double-blind manner, diazepam is included in the study. | CG1: 8 (NR gender) NR age<br><br>CG2: 8 (NR gender) NR age<br><br>CG3: 8 (NR gender) NR age | | (12 total sessions of 30 min each, 3 times a week for a month) | CG2: took Diazepam;<br><br>CG3: took placebo.<br><br>(12 total sessions of 30 min each, 3 times a week for a month) | | *Secondary:*<br><br>NR | | during treatment, which, however, were lost at the follow-up period; BFB although with weaker effects during treatment showed, at follow-up, a long lasting reduction of headache scores even when frontalis activity reached baseline levels; in the false BFB group some decrease of EMG activity during treatment and of headache intensity at follow-up were also observed. |
| **Phillips et al., 1977** | The first question is therefore: Is there a learned decline in muscle tension (i.e., resting levels)? Secondly, is there evidence that this decline results from the use of feedback during the sessions (i.e. treatment levels)? | 15 (NR gender) NR age<br><br>IG: 8 (NR gender) NR age<br><br>CG: 7 (NR gender) NR age | NR;<br><br>Frontalis muscles;<br><br>Temporalis muscles.<br><br>(NR Hz) | Subjects were instructed to reduce the click rate, and preferably to produce silence. If they did so for 15 consecutive seconds during a trial, the experimenter said "Good", and the next trial began with feedback of 3-5 clicks per second again. Thus, following a verbal reward of "Good", subjects were asked to reduce the level of muscle tension even further. If, on the other hand, muscle tension increased so that feedback was above 5 clicks per second for more than 15 consecutive seconds in a trial the sensitivity was reduced at the onset of the next trial in | The pseudo-biofeedback group listened to the taped feedback (inclusive of experimenter verbal rewards) of a successful biofeedback session, while their most abnormal muscle activity was assessed on the same 15-trial basis described for the biofeedback group, they were told that monotonous auditory stimuli were relaxing and would help them clear their minds of stressful thoughts. They would relax further if they could concentrate on the clicks alone.<br><br>(15 trials (45 sec each), with inter-trial intervals (without feedback) of 15 sec | Headache frequency;<br><br>Headache intensity;<br><br>Chronicity of headaches. | *Primary:*<br><br>Chronicity of headaches;<br><br>Headache frequency;<br><br>Headache intensity;<br><br>The most abnormal muscle at rest means the level of resting muscle tension.<br><br>*Secondary:*<br><br>NR | 6 weeks;<br><br>8 weeks. | The BFB treatment led to consistent (over all subjects) and significant reduction in muscle tension level (i.e., retained decrement between sessions, without feedback), and in the variance of these levels. The muscle tension treatment data obtained during BFB trials were consistently below the pre-treatment levels, and by the end of the twelve treatment sessions had dropped to a "normal" level. The decrement of treatment mean level across sessions is not significant. |

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| | | | | order to maintain the clicks at 3-5.<br><br>(15 trials (45 sec each), with inter-trial intervals (without feedback) of 15 sec twice per week for 6 weeks) | twice per week for 6 weeks) | | | | |
| **Rokicki et al., 1997** | To examine the three types of change mechanisms that have been hypothesised to underlie the effectiveness of combined relaxation/ EMG-BFB training. | 41<br>(37F, 6M)<br>16.4 ± NR years<br><br>IG: 29<br>(25F, 4M)<br>19 ± NR years<br><br>CG: 14<br>(12F, 2M) 14.86 ± NR years | EMG activity was recorded using a pair of 10-mm Beckman silver/silver-chloride electrodes (Sensor Medics, Yorba Linda, CA) and a Sensor Medics silver ear clip reference electrode.<br><br>Frontalis muscles;<br><br>Trapezius.<br><br>(10-3000 Hz) | Participants assigned to the EMG biofeedback group received six sessions of combined relaxation/EMG BFB training.<br><br>(6 total sessions, twice weekly) | Participants read a short story and were asked to answer questions about the story. The control group did not have EMG activity measured (3 one hour session). | Headache intensity (0-10);<br><br>Medication intake;<br><br>Free days headache. | *Primary:*<br><br>*Headache measures:*<br><br>Medication intake; Free days headache.<br><br>Cognitive measures:<br><br>ES2 = exteroceptive suppression period of the electrical stimulation self-efficacy and locus of control<br><br>*Secondary:*<br><br>NR | NR | Relaxation/EMG BFB training effectively reduced headache activity: 51.7% of subjects who received relaxation/BFB therapy recorded at least a 50% reduction in headache activity following treatment, while controls failed to improve on any measure. Improvements in headache activity in treated subjects were correlated with increases in self-efficacy induced by BFB training but not with changes in EMG activity or in ES2 durations. |
| **Sargent et al., 1986** | To determine whether increasing blood blow in the hands at will is specifically effective in the treatment of migraine | 136<br>(114F, 22M) 35.7 ± NR years<br><br>IG: 34<br>(NR gender) NR age<br><br>CG1:34<br>(NR gender) NR age<br><br>CG2:34<br>(NR gender) NR age<br><br>CG3:34<br>(NR gender) NR age | NR;<br><br>Frontalis muscles;<br><br>(NR Hz) | The EMG-BFB group focused on the same phrases to help relax the frontalis muscle and received EMG feedback for six sessions, followed by two sessions with no feedback; their instructions pointed out the importance of relaxation training. (22 total sessions, twice weekly for 36 weeks) | CG1: No-Treatment group continued the inactive state; their instructions emphasised the importance of keeping daily records;<br><br>CG2: The Autogenic Phrases group concentrated on the phrases during practice; their instructions stressed the value of autogenic training; | Headache frequency;<br><br>Headache intensity;<br><br>Headache duration;<br><br>Headache location;<br><br>Disability and associated symptoms. | *Primary:*<br><br>Headache assessment EMG and temperature training scores<br><br>*Secondary:*<br><br>NR | 24 weeks. | All groups demonstrated a substantial reduction in the five headache variables over the 36-week trial period for total headache and migraine. |

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| | | | | | CG3: The Thermal BFB group used the same phrases to increase blood flow in the hands and received temperature feedback for six sessions, followed by two sessions with no feedback; their instructions stressed the technique of hand warming. | | | | |
| **Schlutter et al., 1980** | To compare the efficacy of three major psychological treatment methods used with muscle contraction headache. | 48<br>(NR gender)<br>NR age<br><br>IG1: NR<br>(NR gender)<br>NR age<br><br>IG2: NR<br>(NR gender)<br>NR age<br><br>CG: NR<br>(NR gender)<br>NR age | NR;<br><br>Frontalis muscles;<br><br>(NR Hz) | IG1: EMG biofeedback following the methods of Budzynski et al., 1970)<br><br>IG2: EMG feedback identical to that in the second group, plus training in progressive relaxation by Jacobson technique.<br><br>(4 sessions of 1 h each) | CG: hypnosis.<br><br>(4 sessions of 1 h each) | Headache duration (h/week);<br><br>Headache intensity (0-10). | *Primary:*<br><br>Headache duration (h/week);<br><br>Subjective intensity rating;<br><br>Objective intensity ratio.<br><br>*Secondary:*<br><br>NR | 10 weeks;<br><br>14 weeks. | No significant differences were found between treatments on these dependent measures, although all produced significant change in the desired direction. |
| **Sethi et al., 1981** | NR | 13<br>(6M, 7F)<br>16-45 years<br><br>IG: 6<br>(2M, 4F)<br>16-45 years<br><br>CG: 7<br>(4M, 3F)<br>16-45 years | NR;<br><br>Frontalis muscles;<br><br>(NR Hz) | Patients before being placed on IG, were trained for 4 sessions to familiarise them with relaxation by Jacobson relaxation technique. Auditory feedback was provided by the instrument's internal loudspeaker in the form of a series of click sounds. The frequency was proportional to the integrated EMG level. Each patient was helped to achieve relaxation or reduce | Patients taken up on this programme were trained for savasana by a well-trained yoga therapist for 4 sessions. This served as a baseline period during which frequency and severity of headache was also observed. Subsequently the patient exercised shavasana. Subjects were told that they would relax by this procedure, and it would help them unburden stressful | Headache frequency;<br><br>Headache intensity (0-5). | *Primary:*<br><br>Progress of a treatment method evaluated on 0-4 scale for headache and for social adjustment;<br><br>*Secondary:*<br><br>NR | NR | Comparative evaluation of two methods showed no significant change. The average number of sessions taken for savasana was lower than that for EMG-BFB. |

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| | | | | muscle tension with the help of auditory feedback.<br><br>(A 30 min session twice a week for 10 weeks) | thoughts.<br><br>(A 30 min session twice a week for 10 weeks) | | | | |
| **Solbach et al., 1989** | To answer the following questions: is regular home practice necessary for a positive treatment outcome? Which patients are more likely to comply with home practice requirements? Does the frequency and quality of home practice deteriorate over time? | 42<br>(NR gender)<br>NR age<br><br>IG: 17<br>(NR gender)<br>NR age<br><br>CG1: 14<br>(NR gender)<br>NR age<br><br>CG2: 11<br>(NR gender)<br>NR age | NR;<br><br>NR;<br><br>(NR Hz) | Following a 4-week baseline, subjects recorded home practice data during the 8-week training phase;<br>IG performed biofeedback EMG.<br><br>(8 weeks) | Following a 4-week baseline, subjects recorded home practice data during the 8-week training phase;<br>CG1 performed autogenic phases, while CG2 performed thermal biofeedback.<br><br>(8 weeks) | Headache frequency;<br><br>Headache intensity;<br><br>Headache duration;<br><br>Headache disability. | *Primary:*<br><br>11 measures:<br>age;<br>occupational level;<br>education;<br>marital status;<br>referral source;<br>length of headache history;<br>occurrence pattern;<br>family history;<br>headache frequency;<br>clinical assessment;<br>treatment group.<br><br>*Secondary:*<br><br>NR | 6 months. | Younger subjects reported a larger mean % of days in which they experienced a change in the target area than did older subjects and younger subjects reported a larger mean percentage of days in which they detected the presence of general body relaxation than did older subjects. Episodic headache sufferers had a larger mean percentage of days in which they reported the presence of general body relaxation than did the chronic headache sufferers. Improved headache sufferers also had a larger mean percentage of days in which they reported experiencing a change in the target area than did those who did not improve. Reported EMG microvolt changes in the CG1 and temperature changes in the CG2 were examined but no statistical analysis was done due to the small N's. For the 8-week training phase, the average daily |

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| | | | | | | | | | microvolt decrease was 6 microvolts, and the average daily temperature increase was 6.5 degrees. |

BFB: biofeedback; CG: control group; EMG: electromyography; EPI: Eysenck Personality Inventory; FU: follow-Up; min: minutes; h: hours; Hz: hertz; IG: intervention group; NR: not reported; PTI: Pain Total Index; RET: rational emotive therapy; SD: standard deviation; STAIC: State-Trait Anxiety Inventory for Children.

Supplementary Table II.—Table summary of the risk of bias.

| Author, year | Randomization process | Deviations from intended interventions | Missing outcome data | Measurement of the outcome | Selection of the reported result | Overall Bias |
|---|---|---|---|---|---|---|
| Fentress et al., 1986 | + | - | + | + | + | - |
| Kroner-Herwig et al., 1998 | + | - | + | + | + | - |
| Stubberud et al., 2020 | + | + | + | + | + | + |
| Bussone et al., 1998 | + | + | + | + | + | + |
| Abramowitz & Bell, 1985 | + | - | + | + | + | - |
| Andrasyk & Holroyd, 1980 | + | + | + | + | + | + |
| Arena et al., 1995 | + | - | + | - | + | - |
| Bembalgi & Naik, 2013 | + | + | + | + | + | + |
| Bruhn et al., 1979 | + | X | + | + | + | X |
| Budzinsky et al., 1973 | + | + | + | + | + | + |
| Carrobles et al., 1981 | - | - | + | - | + | X |
| Cohen et al., 1980 | + | - | - | + | + | - |
| Cram et al., 1980 | + | X | + | - | + | X |
| Gada et al., 1984 | + | - | + | + | + | - |

| | | | | | | |
|---|---|---|---|---|---|---|
| Gray et al., 1980 | + | + | + | + | + | + |
| Hart & Chichanski, 1981 | + | + | + | + | + | + |
| Hart et al., 1984 | + | X | + | + | + | X |
| Haynes et al., 1975 | + | - | + | + | + | - |
| Huszinski et al., 1984 | + | + | + | + | + | + |
| Kauskik et al., 2005 | + | - | + | + | + | - |
| Lacroix & Corbett, 1990 | + | - | + | + | + | - |
| Lake et al., 1979 | + | - | + | + | + | - |
| Paiva et al., 1981 | + | + | + | + | + | + |
| Phillips et al., 1977 | + | + | + | + | + | + |
| Rokicki et al., 1997 | + | X | + | X | + | X |
| Sargent et al., 1986 | + | - | + | + | + | - |
| Schlutter et al., 1980 | + | - | + | + | + | - |
| Sethi et al., 1981 | + | - | + | X | + | X |
| Solbach et al., 1989 | + | - | + | X | + | X |

Judgement

X High

- Some concerns

+ Low