

**NOTE: This policy has been revised. The revised policy will be effective April 1, 2023. To view the revised policy, [click here](#).**

Medical Policy Manual

Allied Health, Policy No. 32

## ***Biofeedback***

**Effective:** January 1, 2023

**Next Review:** 08/2023

**Last Review:** 08/2022

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Biofeedback is intended to increase awareness and control of certain body functions normally considered to be outside conscious control.

### **MEDICAL POLICY CRITERIA**

**Note:** Services described in this medical policy are not routinely reviewed; however, claims may be subject to audit including but not limited to review of member benefit application, medical appropriateness, frequency utilization, documentation requirements, accurate code selection, and reimbursement. Some devices or services may be subject to the health plan's reimbursement policy manual or may not be covered based on benefit contracts. Claim adjudication is also subject to claim processing guidelines and provider contracts.

- I. Biofeedback as part of the overall treatment plan may be **medically necessary** for one or more of the following indications:
  - A. Migraine or tension headaches
  - B. Stress and/or urge urinary incontinence when administered in conjunction with pelvic floor muscle training (PFMT)

- C. Dyssynergia-type constipation in adults when all of the following criteria (1.-3.) are met:
  - 1. Symptoms of functional constipation that meet all of the following ROME IV criteria (see Policy Guidelines)
  - 2. Objective physiologic evidence of pelvic floor dyssynergia when one or both of the following criteria are met:
    - a. Inappropriate contraction of the pelvic floor muscles
    - b. Less than 20% relaxation of basal resting sphincter pressure by manometry, imaging, or EMG
  - 3. Failed 3-month trial of standard treatments for constipation including laxatives, dietary changes, and pelvic floor exercises
- II. Unsupervised biofeedback in the home setting is considered **investigational** for all indications.
- III. Biofeedback is considered **investigational** for all other indications, including but not limited to the following: chronic pain, fecal incontinence, encopresis, and constipation other than dyssynergia type in adults, fibromyalgia, headaches other than migraine and tension (e.g., cluster headaches), myalgia or muscle pain, neck pain, orofacial pain, shoulder pain, temporomandibular joint disorders, and urinary disorders not meeting criteria, including but not limited to: post- prostatectomy urinary dysfunction, urinary incontinence not administered in conjunction with pelvic floor muscle training (PFMT), urinary retention, vesicoureteral reflux and voiding dysfunction.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## POLICY GUIDELINES

Rome IV diagnostic criteria for functional constipation are as follows:<sup>[1]</sup>

- 1. Must include 2 or more of the following:
  - a. Straining during more than one-fourth (25%) of defecations
  - b. Lumpy or hard stools (Bristol Stool Form Scale 1-2) for more than one-fourth (25%) of defecations
  - c. Sensation of incomplete evacuation for more than one-fourth (25%) of defecations
  - d. Sensation of anorectal obstruction/blockage for more than one-fourth (25%) of defecations
  - e. Manual maneuvers to facilitate more than one-fourth (25%) of defecations (e.g., digital evacuation, support of the pelvic floor)
  - f. Fewer than 3 spontaneous bowel movements per week
- 2. Loose stools are rarely present without the use of laxatives
- 3. Insufficient criteria for irritable bowel syndrome.

## LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision

outcome.

- History and Physical documenting symptoms and treatment specific to policy criteria
- If for constipation, three months of chart note documentation. Indicate if symptom onset is at least six months prior to diagnosis (please include dates).
- Clinical documentation with physiologic evidence of pelvic floor dyssynergia

## CROSS REFERENCES

1. [Neurofeedback](#), Medicine, Policy No. 65
2. [Sphenopalatine Ganglion Block for Headache and Pain](#), Medicine, Policy No. 160
3. [Percutaneous Neuromodulation Therapy \(PNT\)](#), Surgery, Policy No. 44

## BACKGROUND

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. The technique involves the feedback of a variety of types of information not normally available to the patient, followed by a concerted effort on the part of the patient to use this feedback to help alter the physiological process in some specific way. Biofeedback training is done either in individual or group sessions, alone, or in combination with other behavioral therapies designed to teach relaxation. A typical program consists of 10 to 20 training sessions of 30 minutes each. Training sessions are performed in a quiet, non-arousing environment. Subjects are instructed to use mental techniques to affect the physiologic variable monitored, and feedback is provided for successful alteration of that physiologic parameter. The feedback may be in the form of lights or tone, verbal praise, or other auditory or visual stimuli.

## REGULATORY STATUS

A variety of biofeedback devices are cleared for marketing through the Food and Drug Administration's (FDA) 510(k) process. The FDA defines a biofeedback device as "an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters." Freespira from Palo Alto Health Sciences, Inc. is an example of a biofeedback device that has received FDA approval (K180173).

## EVIDENCE SUMMARY

There are several methodologic challenges that arise in assessing biofeedback for any indication. For example, most interventions that include biofeedback are multimodal and include relaxation and behavioral instruction which may have effects separate from those that may occur due to biofeedback. While studies may report a beneficial effect of multimodality treatment, without appropriate control conditions, it is difficult to isolate the specific contribution of biofeedback to the overall treatment effect. In addition, behavioral therapies (non-drug treatments including biofeedback) result in both nonspecific and specific therapeutic effects. Nonspecific effects, sometimes called the placebo effect, occur as a result of therapist contact, positive expectancies on the part of the patient and therapist, and other beneficial effects that occur as a result of being a patient in a therapeutic environment. Specific effects are those that occur only because of the active treatment, above any nonspecific effects that may be present.

In order to isolate the independent contribution of biofeedback on health outcomes (specific

effects) and properly control for nonspecific treatment effects, well-designed randomized controlled trials (RCT) with the following attributes are necessary:

- Randomization helps to achieve equal distribution of individual differences by randomly assigning patients to either biofeedback or sham-biofeedback treatment groups. This promotes the equal distribution of patient characteristics across the two study groups. Consequently, any observed differences in the outcome may, with reasonable assuredness, be attributed to the treatment under investigation.
- A comparable sham control group helps control for expected high placebo effects as well as for the variable natural history of the condition being treated.
- Blinding of study participants, caregivers, and investigators to active or sham assignments helps control for bias for or against the treatment. Blinding assures that placebo effects do not get interpreted as true treatment effects.
- Small studies limit the ability to rule out chance as an explanation of study findings.
- Follow-up periods must be long enough to determine the durability of any treatment effects.

*Therefore, the focus of the evidence review for biofeedback for all indications is on RCTs with the attributes noted above.*

## ASTHMA

### SYSTEMATIC REVIEWS

Yorke (2015) published a SR of studies evaluating nonpharmacologic interventions for the treatment of adults with asthma.<sup>[2]</sup> The literature search, conducted through May 2014, identified 23 studies for inclusion. The nonpharmacologic interventions were organized into groups: relaxation-based therapies (n=9 studies); cognitive behavioral therapies (n=5 studies); biofeedback techniques (n=3 studies); and mindfulness (n=1 study). Five studies incorporated multicomponent interventions. The three biofeedback RCTs used different techniques: exhaled carbon dioxide capnography (pooled n=12)<sup>[3]</sup>; HRV using a physiograph (pooled n=94 patients)<sup>[4]</sup>; and respiratory sinus arrhythmia by electrocardiographic feedback and muscle tension by electromyography (EMG; pooled n=17 patients).<sup>[5]</sup> Common outcomes in the 3 studies included peak expiratory flow and respiratory impedance. Two of the trials reported on medication use. While differences were detected in exhaled carbon dioxide, HRV, and muscle tension, no changes in forced expiratory volume in one second (FEV<sub>1</sub>) were found and medication use decreased in only one trial. Reviewers concluded that larger sample sizes were needed to demonstrate effects and that, while certain parameters that patients received biofeedback on may have differed between treatment groups, those differences did not translate into meaningful clinical benefits.

### RANDOMIZED CONTROLLED TRIALS

Lehrer and colleagues<sup>[4]</sup> reported the results of 94 asthma patients randomized to one of the following four groups:

1. “Full protocol” including heart rate variability (HRV) biofeedback and training in pursed-lips abdominal breathing with prolonged exhalation;

2. HRV biofeedback alone;
3. Placebo biofeedback involving bogus “subliminal suggestions designed to help asthma”, with no other details provided and no actual suggestions given plus biofeedback training to alternately increase and decrease frontal EEG alpha rhythms; and
4. A waiting list control group.

Although reported improvement was greater in the two treatment groups, scientific conclusions cannot be drawn from this data due to several limitations, as discussed in the [Background](#) section above, including possible selection bias due to lack of randomization, short study duration, lack of follow-up to assess long-term effects, and differences between groups in task involvement and assessment frequency. The authors concluded that further research is needed. They advise caution in the use biofeedback for the treatment of asthma until the mechanisms of action are better understood and the long-term effects have been documented.

## **SECTION SUMMARY**

There is insufficient evidence from SRs and RCTs that biofeedback improves outcomes in individuals with asthma. Additional evidence is needed from well-designed comparative studies.

## **AUTISM SPECTRUM DISORDER**

Autism Spectrum Disorders (ASD) can vary in severity of disease and therefore treatments utilized to treat the disease, making it difficult to isolate outcomes associated with biofeedback. The following literature review for biofeedback as a treatment of ASD focuses on SRs and RCTs.

### **SYSTEMATIC REVIEW**

Coben and Myers (2010) reviewed the literature on EEG biofeedback for ASDs.<sup>[6]</sup> The authors identified two published small, non-RCTs evaluating EEG biofeedback in the treatment of ASDs. As described in the review, a study published by Jarusiewicz and colleagues in 2002 compared treatment with 20 to 69 sessions of biofeedback in 12 autistic children to a matched control group that did not receive biofeedback. Mean reduction in autistic symptoms, as measured by the Autism Treatment Evaluation Checklist (ATEC), was 26% in the biofeedback group and 3% in the comparison group; this difference was statistically significant. The other study was published by Coben and Padolsky in 2007. It compared 20 sessions of EEG biofeedback in 37 patients to a waiting-list control group. After treatment, parents reported reduction in symptoms in 89% of the treatment group compared to 17% of the control group (p-value not reported). Studies differed in their biofeedback protocols and number of sessions. The review article concluded that RCTs are needed to determine the effectiveness of biofeedback to treat ASDs.

### **RANDOMIZED CONTROLLED TRIALS**

Yang (2015) conducted a RCT to explore the effects of visual condition and target size during four reach-to-grasp tasks between 20 autistic and 20 matched control children subjects.<sup>[7]</sup> The autistic children showed longer movement time, larger normalized jerk score, more movement when compared to controls, especially in non-visual feedback and small target blocks. This

study is limited by the small sample size and other methodological considerations making it hard to determine the efficacy of visual effects for autism.

Kouijzer (2013) published a RCT evaluating electroencephalography (EEG) biofeedback as a treatment for ASD.<sup>[8]</sup> The trial included 35 teenagers between 12 and 18 years-old with confirmed diagnoses of ASD. Participants were randomly assigned to receive EEG biofeedback (n=13), skin conductance biofeedback (n=12), or a waiting-list control group (n=13). The biofeedback interventions included 40 sessions provided twice a week. Patients and parents in the biofeedback groups but not on the waiting-list were blinded to treatment allocation. The primary outcome measure was change in symptoms at three months as measured by the total score on the Social Communication Questionnaire (SCQ) which has a potential range of 0 to 36. In the primary analysis, the investigators only included participants who successfully influenced their EEG activity (called “EEG-regulators”) in the primary analysis. The justification for this was to be able to identify the specific effects of biofeedback on symptoms. Among the 19 of 35 (54%) regulators, there was no statistically significant difference in the SCQ scores between participants treated with EEG- or skin-conductance biofeedback. The investigators evaluated non-specific effects of EEG biofeedback by examining the SCQ scores among EEG-non-regulators as rated by the parents. There was no statistically significant difference in scores among participants in the EEG biofeedback group, the skin conductance biofeedback group and the control group.

## **SECTION SUMMARY**

There is insufficient evidence from SRs and RCTs that biofeedback improves outcomes in individuals with ASDs. The scientific evidence on the effectiveness of biofeedback for treatment of autism consists of one small RCT and a limited number of small, non-randomized studies. The RCT did not report a significant benefit of biofeedback on autism-related symptoms.

## **BELL’S PALSY (IDIOPATHIC FACIAL PARALYSIS)**

### **SYSTEMATIC REVIEWS**

A 2011 Cochrane SR of physical therapy modalities for the treatment of Bell’s palsy.<sup>[9]</sup> The authors identified two case series and one small RCT. However, no analysis of these studies was performed because they did not meet the minimum methodological quality to be included in the review.

Cardoso (2008) examined the effects of facial exercises associated either with mirror or EMG biofeedback with respect to complications of delayed recovery in Bell’s palsy.<sup>[10]</sup> Patients with unilateral idiopathic facial palsy treated with facial exercises associated with mirror and/or EMG biofeedback were included in this review. Four studies (n=132) met the eligibility criteria. The studies described mime therapy versus control (n=50), mirror biofeedback exercise versus control (n=27), “small” mirror movements versus conventional neuromuscular retraining (n=10), and EMG biofeedback plus mirror training versus mirror training alone. The treatment length varied from one to twelve months. The authors concluded that “...because of the small number of RCTs, it was not possible to analyze if the exercises, associated either with mirror or EMG biofeedback, were effective. In summary, the available evidence from ran RCTs is not yet strong enough to become integrated into clinical practice.”

### **RANDOMIZED CONTROLLED TRIALS**



No RCTs identified after the above SRs.

## SECTION SUMMARY

Current evidence from small RCTs with variable biofeedback protocols and type of comparison interventions is insufficient to permit conclusions on the impact of biofeedback on Bell's palsy.

## BRUXISM AND SLEEP BRUXISM

### SYSTEMATIC REVIEWS

Manfredini (2015) published a SR which included 14 studies, 12 of the studies were RCTs.<sup>[11]</sup> Two of the studies evaluated bruxism. The authors concluded that the potential benefit of biofeedback (BF) and cognitive-behavioral (CB) approaches to sleep bruxism management is not fully supported.

Wang (2013) published a SR of RCT and non-RCTs on biofeedback treatment for sleep bruxism.<sup>[12]</sup> The full text of 17 articles was reviewed and seven studies with a total of 240 participants met the inclusion criteria. Studies were generally small; only two included more than 50 participants. Four studies used audio biofeedback, two used contingent electrical stimulation and 1 used visual biofeedback. Treatment duration ranged from one night to six weeks. In four of the studies, the duration of treatment was two weeks. Three of the studies were considered to be at moderate risk of bias and the other four were considered to be at high-risk of bias. The primary outcome of the analysis was the number of sleep bruxism episodes per hour detected by EMG recording. Only two studies (total n=27) reported this outcome and had data suitable for meta-analysis. A pooled analysis did not find a statistically significant difference between the biofeedback and control groups; mean difference: -4.47 (95% CI: -12.33 to 3.38). Findings were not pooled for any other outcomes.

### RANDOMIZED CONTROLLED TRIALS

Sato (2015) published a RCT limited in size on the use of EMG biofeedback training for daytime clenching and its effect on sleep bruxism.<sup>[13]</sup> Patients were monitored for five hours of daytime and night time and were randomized to EMG biofeedback (n=7) or to a control group (n=5). Patients in the biofeedback group received a small auditory signal in the daytime when clenching activity was detected. There were significant decreases in EMG events during weeks two and three in the biofeedback group during the daytime, and the decreases in events carried over into the night time. There were no decreases in EMG events in the control group.

## SECTION SUMMARY

There is insufficient evidence from SRs and RCTs that biofeedback improves outcomes in individuals with bruxism. Additional evidence is needed from well-designed comparative studies.

## CHRONIC PAIN (NON-HEADACHE)

As discussed in the [Background](#) section above, the focus of the evidence review was on RCTs. This study design is particularly important when studying treatments for pain. The most clinically relevant outcomes of therapy for pain are improvement in symptoms, function, and quality of life. These outcomes are subjective and can be influenced by nonspecific effects such as placebo response and the natural history of the disease. Randomized treatment

allocation and the inclusion of a control group are needed to isolate the effect of biofeedback therapy.

## **GENERAL NON-HEADACHE PAIN**

### **Systematic Reviews**

A Cochrane SR by Williams on psychological therapies (cognitive-behavioral therapy [CBT] and behavioral therapy, including biofeedback) for chronic non-headache pain in adults was updated in 2012.<sup>[14]</sup> Forty-two trials provided analyzable data, thirteen of which had not been included in previous updates of this review. The SR found that although the quality of trial design had improved over time, the quality of treatments, reporting, or both had not improved. CBT (not behavioral therapy) had weak effects in improving pain, but only immediately following treatment. CBT also had small effects on pain-related disability, altering mood, and catastrophizing outcomes compared with usual treatment or waiting list patients, with some maintenance at six months follow-up. However, it was not possible to isolate the results for the individual components of CBT, including biofeedback. Behavioral therapy had no effect on mood but showed an effect on catastrophizing immediately post-treatment. The authors recommended against future general RCTs, recommending instead, studies to identify which components of CBT work for which type of patient.

Another Cochrane SR review by Eccleston and colleagues evaluated psychological therapies for the management of chronic and recurrent pain in children and adolescents. Included studies were RCTs with at least 10 participants in each arm. Although psychological therapies were found to improve pain, only one of the five studies on non-headache pain evaluated biofeedback.

Palermo conducted an SR of RCTs to update previously published SRs on psychological therapies for management of chronic non-headache pain in children and adolescents was published by Palermo and colleagues in 2010.<sup>[15]</sup> RCTs included in previous SRs were automatically eligible for inclusion in this SR. The review did not identify any new RCTs that had not been included in previous SRs. It was not possible to isolate the results of the individual components of the psychological therapies, including biofeedback.

### **Randomized Controlled Trials**

No RCTs were identified that were published after the above SRs.

## **ARTHRITIS**

### **Systematic Reviews**

Richards (2017) published a SR evaluating the application of real-time biofeedback to reduce knee adduction movement (KAM) during gait training, for patients with knee osteoarthritis (KOA).<sup>[16]</sup> Twelve studies met the inclusion criteria. The authors concluded there are limited controlled studies, but found value for further research in the outcomes of biofeedback to reduce KAM.

In a SR with meta-analysis of psychological interventions for rheumatoid arthritis including relaxation, biofeedback, and cognitive-behavioral therapy, Astin and colleagues concluded that psychological interventions may be important adjunctive therapies in rheumatoid arthritis treatment.<sup>[17]</sup> In the 25 studies analyzed, significant pooled effect sizes were found for pain



after an intervention. However, the same effect was not seen long term, and the meta-analysis did not isolate biofeedback from other psychological interventions. Therefore, the specific effects of biofeedback, as discussed in the [Background](#) section above, could not be isolated.

## **Randomized Controlled Trials**

Eid (2016) published a RCT that evaluated the outcomes of electromyographic (EMG) biofeedback training on pain, quadriceps strength and functional ability for 11 boys and 25 girls with polyarticular juvenile rheumatoid arthritis (JRA).<sup>[18]</sup> Children were assigned to the EMG biofeedback group (n=18) or the control group (n=18). Treatments occurred over 12 weeks, with evaluation at six and 12 weeks. Both groups showed significant improvement at 12 weeks.

## **FIBROMYALGIA**

### **Systematic Reviews**

In 2015 a Cochrane SR was published by Theodom examining mind and body therapy for fibromyalgia. Sixty-one trials were included in the review.<sup>[19]</sup> The study participants were predominately women and their nature of fibromyalgia varied from mild to severe across the study population. No adverse events were reported. The authors found there was very low quality evidence that biofeedback in comparison to usual care controls had an effect on physical functioning, (SMD -0.1, 95% CI -0.4 to 0.3, - 1.2% absolute change, 1 point shift on a 0-100 scale) pain (SMD -2.6, 95% CI -91.3 to 86.1, -2.6% absolute change, and mood ((SMD 0.1, 95% CI -0.3 to 0.5, 1.9% absolute change, less than 1 point shift on a 0 to 90 scale) post-intervention. Due to the very low quality evidence, it is unclear what role biofeedback has fibromyalgia.

In 2013 Glombiewski published the results of a meta-analysis that included three studies on EEG-biofeedback (neurofeedback) and four studies on EMG-biofeedback for fibromyalgia (N=321).<sup>[20]</sup> Studies in which biofeedback was evaluated only as part of multicomponent interventions were excluded from the review. A sham intervention was used as a control condition in four studies, two using EEG biofeedback and two using EMG- biofeedback. A pooled analysis was conducted for each therapy. EMG-biofeedback was reported to have significantly reduced pain intensity compared to control groups (effect size, Hedges *g*: 0.86, 95% CI, 0.11 to 0.62). Pooled analyses of studies of EMG and EEG biofeedback did not find a significant benefit of the intervention on other outcomes including sleep problems, depression and health-related quality of life. None of the studies included in this review were high quality, with risk of bias assigned by the authors as either unclear or high for all included studies. In addition, all of the studies reported on short-term outcomes, resulting in a lack of evidence on whether longer-term outcomes are improved. The authors recommended further research focused on long-term effects and predictors of treatment response.

### **Randomized Controlled Trials**

No RCTs identified after the SR above.

## **KNEE PAIN**

### **Systematic Reviews**

A number of SRs have been published that included trials of biofeedback in the treatment of anterior knee pain<sup>[21]</sup>, patellofemoral pain syndrome,<sup>[22]</sup> and in post-menisal repair rehabilitation.<sup>[22]</sup> Mixed results have been reported by the SRs, but no standardized treatment protocols or patient selection criteria have been established for biofeedback for knee pain of any etiology.

## **Randomized Controlled Trials**

No RCTs were published after the above SR.

## **LOW BACK PAIN**

### **Systematic Review**

Sielski (2017) published a SR evaluating the impact of biofeedback for chronic back pain.<sup>[23]</sup> Twenty-one studies met all inclusion criteria, one of which had to be biofeedback at least 25% of the time. Outcomes were determined for pain, disability, depression, reduced muscle tension, and coping skills. The authors concluded that although the outcomes of biofeedback are promising, the SR had limitations including heterogeneity of how biofeedback and back pain were defined and the positive results should be interpreted with caution.

Qaseem (2017) published a guideline from the American College of Physicians (ACP) that by using the ACP was based on a SR of RCTs and SRs published through April 2015.<sup>[24]</sup> For patients with acute or sub-acute low back pain, biofeedback was not mentioned. For patients with chronic low back pain the recommendation was to initially try nonpharmacological treatments including biofeedback based on “low quality evidence”. For patients with chronic low back pain who have not responded to nonpharmacological treatments, pharmacological treatment may be considered.

Haines (2017) published an economic evaluation that was done alongside a pilot randomized trial that evaluated motion-sensor biofeedback for sub-acute and chronic low back pain over 12 months.<sup>[25]</sup> Patients received motion-sensor biofeedback with guideline based care (n=38) or guideline based care alone (n=45) over ten weeks and completed a three, six, and 12 month assessment. The authors concluded that motion-sensor biofeedback is both clinically and economically effective, but more studies are needed.

Daffada (2015) conducted a SR to identify and assess the current evidence regarding the effectiveness of interventions (i.e. graded motor imagery and mirror visual feedback) which target cortical remapping in the management of chronic low back pain (CLBP).<sup>[26]</sup> Five articles were included in the review, which were comprised of three RCTs, one randomized cross-over study, and one multiple case study design. Although the authors report these interventions, including visual feedback, could be effective, the paucity of literature, small sample sizes, and methodological constraints of the studies included in the review make it difficult to determine the effectiveness of the interventions in the management of CLBP.

A 2010 Cochrane review<sup>[27]</sup> on behavioral treatments for chronic low-back pain included a meta-analysis of three small RCTs<sup>[28-31]</sup> comparing electromyography (EMG) biofeedback to a waiting-list control group. These studies were graded as low to very low quality due to methodological limitations and imprecision. In the pooled analysis there were a total of 34 patients in the intervention group and 30 patients in the control group. The standard mean difference in short-term pain was -0.80 (95% confidence interval [CI]:-1.32 to -0.28); this difference was statistically significant favoring the biofeedback group. One additional RCT was

not included in the pooled analysis due to differences in reporting.<sup>[28]</sup> This small RCT (n=44) was determined to have a low risk of bias and reported no significant differences in outcomes between groups. The Cochrane review did not conduct meta-analyses of trials comparing biofeedback to sham biofeedback.

## **Randomized Controlled Trials**

Tan (2015) conducted a four arm RCT of hypnosis compared with biofeedback for 100 veterans adults with chronic low back pain (CLBP).<sup>[32]</sup> Group one included an eight-session self-hypnosis training intervention without audio recordings for home practice; group two consisted of an eight-session self-hypnosis training intervention with recordings; group three had a two-session self-hypnosis training intervention with recordings and brief weekly reminder telephone calls; and group four had an eight-session active biofeedback control intervention. All four groups reported significant pre-to post-treatment improvements in pain intensity, pain interference, and sleep quality. This study was limited by the small sample size and other methodological constraints making it hard to determine the efficacy of biofeedback for adults with CLBP.

In a 2010 study published after the above Cochrane SR, Kapitza compared the efficacy of respiratory biofeedback to sham biofeedback in 42 patients with lower back pain.<sup>[33]</sup> All participants were instructed to perform daily breathing exercises with a portable respiratory feedback machine; exercises were performed for 30 minutes on 15 consecutive days. Patients were randomized to an intervention group that received visual and auditory feedback of their breathing exercises or a control group that received a proxy signal imitating breathing biofeedback. Patients recorded pain levels in a diary three times a day, measuring pain on a visual analogue scale (VAS). Both groups showed reduction in pain levels at the end of the intervention period and at the three month follow-up, but there were no significant differences in pain between groups. For example, the mean change in pain with activity three months after the intervention was a reduction in 1.12 points on a 10-point VAS scale in the intervention group and 0.96 points in the sham control group;  $p>0.05$ . The mean change in pain at rest after three months was a reduction of 0.79 points in the intervention group and 0.49 points in the control group;  $p>0.05$ .

Another 2010 RCT, by Glombiewski, assessed whether the addition of EMG biofeedback to CBT improved outcomes in 128 patients with lower back pain.<sup>[34]</sup> Patients with musculoskeletal pain of the low, mid, or upper back, with pain duration of at least six months on most days of the week, were randomized to CBT, CBT plus biofeedback, or a waiting-list control; 116 patients began the 1-hour weekly sessions (17-25 treatments) and were included in the final analysis. CBT alone included breathing exercises and progressive muscle relaxation; biofeedback was used for 40% of the CBT treatment time in the combined treatment condition. Both treatments were found to improve outcomes including pain intensity compared to a waiting-list control (moderate effect size of 0.66 for pain intensity in the CBT plus biofeedback group). However, the addition of biofeedback did not improve outcomes over CBT alone.

## **NECK AND SHOULDER PAIN**

### **Systematic Reviews**

Campo (2021) published a systematic review and meta-analysis that evaluated the effectiveness of biofeedback for improving pain, disability, and work ability in adults with neck pain.<sup>[35]</sup> The review included 15 RCTs with eight studies utilizing EMG biofeedback and seven

studies pressure biofeedback. There was no restriction on the control intervention (eg, no treatment, placebo, active treatment) or co-intervention, provided the independent effects of biofeedback could be elucidated. Results suggest that biofeedback has a moderate effect on reducing short-term disability and a small effect on reducing intermediate-term disability with no effect on pain or work ability in the short- and intermediate-term. Of note, there were a variety of control interventions across included studies (eg, exercise, electroacupuncture, electrotherapy, education) with few studies directly comparing biofeedback to no treatment or placebo.

Kamonseki (2021) completed a systematic review and meta-analysis of 5 RCTs (N=272) that examined the effects of EMG biofeedback for shoulder pain and function.<sup>[36]</sup> Very-low quality of evidence found that electromyographic biofeedback was not superior to control for reducing shoulder pain (standardized mean differences = -0.21, 95% confidence interval: -0.67 to 0.24, p=0.36) or shoulder function (standardized mean differences = -0.11, 95% confidence interval: -0.41 to 0.19, p=0.48). The authors state the very low quality of evidence does not permit a definitive recommendation regarding EMG biofeedback in the treatment of shoulder pain.

Shearer (2016) published a SR evaluating the impact of psychological interventions, one of which was biofeedback for neck pain and associated disorders (NAD) and whiplash disorders.<sup>[37]</sup> The SR included RCTs, cohort and case control studies. No clear positive effects were seen for biofeedback and the authors noted more sound methodological research is needed.

Hesselstrand (2015) published a SR of 19 studies called Occupational Therapy Interventions in Chronic Pain-A SR.<sup>[38]</sup> One RCT addressed surface EMG biofeedback training for persons with neck and shoulder complaints after whiplash-associated disorders, concerning activities of daily living and pain. The SR concluded that no support exists for the effectiveness of electromyographic biofeedback training as a supplement and that more studies are needed to confirm this result.

### **Randomized Controlled Trial**

Ma (2011) published an RCT that included 72 patients with chronic (at least three months) computer work-related neck and shoulder pain.<sup>[39]</sup> Patients were randomized to one of four six-week interventions: Biofeedback, exercise, passive treatment (e.g., hot packs), or a control group receiving only an educational pamphlet. Members of the biofeedback group were given a portable EMG biofeedback machine and were instructed to use it for two hours daily while performing computer work. The active exercise group was given an exercise routine to perform on their own for no longer than 20 minutes, four times a day. Sixty of 72 (83%) participants were available for the post-intervention follow-up assessment (n=15 per group). At the end of the intervention, the average VAS score and neck disability index (NDI) scores were significantly lower in the biofeedback group than in the other three groups. For example, the mean VAS post-intervention was 1.87 (standard deviation [SD]: 0.74) in the biofeedback group and 2.10 (SD: 1.34) in the active exercise group (p< 0.05).

This study found a short-term benefit of a biofeedback intervention, but the magnitude of difference in the VAS scores and the NDI index was small and of uncertain clinical significance. In addition, there were several methodologic limitations. The study was of small size and had a substantial number of dropouts; data were available on only 39 of 72 (54%) participants at six months. The interventions were not balanced in intensity, as the biofeedback intervention was more intensive (two hours per day) than the other interventions, such as the

passive treatment arm, which received two 15-minute sessions per week. Long-term data were not available due to the low follow-up rate, which at six months was too small for meaningful analysis.

## **OROFACIAL PAIN (INCLUDING TEMPOROMANDIBULAR JOINT DISORDER)**

### **Systematic Reviews**

A 2011 Cochrane SR identified 17 trials evaluating non-pharmacological psychological interventions for adults with chronic orofacial pain (e.g., temporomandibular joint (TMJ) disorder).<sup>[40]</sup> For the outcome short-term pain relief (three months or less), there was a significantly greater reduction in pain with interventions that combined CBT and biofeedback compared to usual care (two studies). However, there was not a significant benefit of a combined CBT/biofeedback on longer-term i.e., six-month pain relief, and there were no studies that compared CBT alone to CBT combined with biofeedback. For biofeedback-only interventions, a pooled analysis of two studies on short-term pain relief did not find a significant benefit compared to usual care. There was only one study reporting long-term pain relief after a biofeedback-only intervention, so a pooled analysis could not be conducted. The authors concluded that there is weak evidence to support psychosocial interventions for managing chronic orofacial pain and the most promising evidence is for CBT, with or without biofeedback. They noted that the trials in the review were few in number and had a high risk of bias, and they recommended additional high-quality trials.

The conclusions of the Cochrane review are similar to previous SRs on treatment of TMJ disorder. The reviews also concluded that there is weak evidence that psychosocial/physical therapy interventions, including biofeedback among others, are beneficial for treating TMJ but that there were few studies and they tended to be of poor methodologic quality. For example, Medicott and colleagues recommended caution in interpreting results due to heterogeneity in study design and interventions used.<sup>[41]</sup> Since biofeedback was not isolated from other therapies, no conclusions could be reached for biofeedback alone. Based on two poor-quality RCTs, McNeely and colleagues concluded that biofeedback did not reduce pain more than relaxation or occlusal splint therapy for TMJ, but did improve oral opening when compared with occlusal splints.<sup>[42]</sup>

### **Randomized Controlled Trials**

No RCTs identified after the above SR.

## **SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)**

### **Systematic Reviews**

No SRs were identified for biofeedback for the treatment of SLE.

### **Randomized Controlled Trial**

In an RCT of 92 patients with Systemic Lupus Erythematosus (SLE), Greco and colleagues reported that patients treated with six sessions of biofeedback-assisted cognitive-behavioral treatment for stress reduction had a statistically significant greater improvement in pain post treatment than a symptom-monitoring support group ( $p=0.044$ ) and a usual care group ( $p=0.028$ ).<sup>[43]</sup> However, these improvements in pain were not sustained at a nine-month follow-

up and further studies are needed to determine the incremental benefits of biofeedback-assisted cognitive-behavioral treatment over other interventions in SLE patients.

## **RECURRENT ABDOMINAL PAIN**

### **Systematic Reviews**

No SRs were identified using biofeedback for the treatment of recurrent abdominal pain.

### **Randomized Controlled Trial**

Humphrey's and Everts randomly assigned 64 patients with recurrent abdominal pain to groups treated with: 1) increased dietary fiber; 2) fiber and biofeedback; 3) fiber, biofeedback, and cognitive-behavioral therapy; and 4) fiber, biofeedback, cognitive-behavioral therapy, and parental support.<sup>[44]</sup> The three multi-component treatment groups were similar and had better pain reduction than the fiber-only group. This study does not address placebo effects. In a SR of recurrent abdominal pain therapies in children, Weider and colleagues concluded that behavioral interventions (cognitive-behavioral therapy and biofeedback) had a general positive effect on nonspecific recurrent abdominal pain and were safe.<sup>[45]</sup> However, the specific effects of biofeedback were not isolated in this SR.

## **VESTIBULODYNIA/VULVODYNIA/VULVAR VESTIBULITIS**

### **Systematic Reviews**

Morin published a SR to evaluate the outcomes of different physical therapies, one of which was biofeedback for women with provoked vestibulodynia.<sup>[46]</sup> The SR included RCTs, prospective and retrospective studies, case reports and study protocols, most of which had methodological limitations. The authors concluded more well designed RCTs are needed.

### **Randomized Controlled Trial**

An RCT by Bergeron of 78 patients with vulvar vestibulitis compared biofeedback, surgery and cognitive-behavioral therapy.<sup>[47]</sup> Surgery patients had significantly better pain scores than patients who received biofeedback or cognitive-behavioral therapy. No placebo treatment was used.

## **OTHER CHRONIC PAIN**

Other pain for which there are no publications sufficient to demonstrate the effectiveness of biofeedback include muscle pain or myalgia.

## **SECTION SUMMARY**

The current evidence base is insufficient to allow scientific conclusions concerning the contribution of biofeedback to improvements in health outcomes for the treatment of chronic non-headache pain. [[Headache](#) is discussed separately below]

## **DEPRESSION, ANXIETY, AND POST-TRAUMATIC STRESS DISORDERS**

### **Systematic Reviews and Technology Assessments**

In 2018, the Canadian Agency for Drugs and Technology in Health (CADTH) published an updated "Post-Traumatic Stress Disorder: Summary of Evidence of the Clinical Effectiveness



of Treatments”.[48] They reviewed 26 treatments, one of which was biofeedback. They continued their stance that there is no evidence-based guidelines for the treatment of any mood or anxiety disorders. Additional well-designed, controlled clinical studies are needed to determine the clinical effectiveness of biofeedback on PTSD.

A 2017 CADTH evidence report on biofeedback for mood and anxiety disorders states the following:[49]

Evidence from single randomized controlled trials suggests that compared with no treatment there is a statistically significant improvement in symptoms with neurofeedback treatment in patients with post-traumatic stress disorder (PTSD) or generalized anxiety disorder (GAD).

A single randomized controlled trial (RCT) showed that for patients with PTSD there was improvement in symptoms with biofeedback (BF) plus treatment as usual (TAU) and also with TAU alone but the improvement occurred faster in the BF plus TAU group.

A single RCT showed that for patients with PTSD there were no between group differences for BF and various mindfulness related treatment modalities. A single RCT showed that for patients with major depressive disorder, there was a statistically significant improvement in depression with BF plus TAU.

Results need to be interpreted in the light of limitations (such as small sample size, lack of randomization details, lack of reporting of adverse events, lack of long-term data).

No relevant studies on the clinical effectiveness of biofeedback using home equipment for treatment of PTSD, GAD, or depression without continued support from health professionals were identified.

No relevant evidence based guidelines regarding the use of neurofeedback or biofeedback for the treatment of PTSD, GAD, or depression were identified.

Goessl (2017) published a SR on the effect of heart rate variability (HRV) biofeedback training in patients with stress and anxiety.[50] HRV is a measure of cardiac vagal tone. Low HRV is associated with certain psychological states such as anxiety. The literature search identified 24 studies (total N=484 patients), published between 1976 and 2015, for inclusion. Sample sizes ranged from five to 106 patients (median, 14 patients). The Cochrane risk of bias tool was used to assess study quality. Many studies had high or unclear risk of bias due to the following factors: inadequate randomization descriptions, improper randomization, undescribed allocation concealment, and missing data that was either not described or mishandled; 13 studies included a comparison group (six waitlist, three standard of care, two sham, one daily thought record, one progressive muscle relaxation). The average within-group effect size among the 24 studies, measured by Hedges’ *g*, was 0.81, indicating a large effect on anxiety. The average between-group effect size among the 13 studies with comparators, also measured by Hedges’ *g*, was 0.83, indicating HRV had a larger effect on anxiety than the comparators.

Schoenberg and David (2014) published a systematic review (SR) on biofeedback for psychiatric disorders, one of which was anxiety.[51] They identified 227 articles and 63 met the criteria for review. The authors concluded that development of standardized controlled methodology protocols tailored for specific disorders and guidelines are needed to determine the benefit of biofeedback on health outcomes for those with anxiety.

## Randomized Controlled Trials

In addition to those included in the systematic reviews, the following RCTs have been published. Maynard (2021) compared respiratory and heart rate biofeedback plus usual care to usual care alone in 36 patients with moderate to severe depression or dysthymia.<sup>[52]</sup> After six weeks (six sessions of biofeedback training), the biofeedback plus usual care group had less severe depression as measured by the Beck Depression Inventory (BDI) than the usual care alone group.

A preliminary open-label RCT by Park and Jung (2020) compared respiratory sinus arrhythmia biofeedback plus usual care to usual care alone in 30 patients with major depressive disorder.<sup>[53]</sup> After four weeks (six sessions of biofeedback), the biofeedback plus usual care group had greater improvements in Hamilton Depression Rating Scale (HAM-D) scores compared to the group receiving usual care alone. Improvements in other clinical measures, including the BDI, were not significantly different between groups.

Chen (2016) published an RCT comparing diaphragmatic breathing relaxation (DBR) with routine respiration activities in the treatment of 46 patients with anxiety.<sup>[54]</sup> DBR is a technique that uses diaphragm muscle contractions to force air downward into the body, increasing diaphragm length and breathing efficiency. Outcomes were anxiety level, measured by Beck Anxiety Inventory, and four physiological measures (skin conductivity, peripheral blood flow, heart rate, breathing rate). All patients participated in an individualized eight-week course in breathing relaxation, but only 30 completed it. Fifteen were randomized to DBR training and 15 to routine breathing relaxation training. Researchers and patients were blinded to randomization, with only the trainer being aware of group allocation. After eight weeks, the DBR group experienced statistically significant decreases in Beck Anxiety Inventory scores compared with baseline, while the control group did not experience significant decreases from baseline. The DBR group also experienced significant improvements in all four physiological measurements, while the control group did not. The authors noted this therapy is promising, but more well-controlled studies are needed.

A RCT by Meuret (2010) included 41 patients with panic disorder and agoraphobia who were randomized to receive four weeks of capnometry-assisted respiratory training (Freespira) or cognitive training.<sup>[55]</sup> Although capnometry-assisted respiratory training, but not cognitive training, was associated with a shift from hypocapnic to normocapnic levels, reductions in panic symptom severity and panic-related cognitions as well as improvements in perceived control were significant and comparable in both treatment groups.

## FECAL INCONTINENCE AND CONSTIPATION

The relevant clinical outcome in studies of biofeedback as a treatment of fecal incontinence, encopresis, and constipation should be the overall change in the bowel symptoms. Reduction in episodes of fecal incontinence, encopresis, and constipation, and an increase in voluntary bowel movements as a result of biofeedback are the primary clinical outcomes of interest. Patient symptoms are usually assessed through diary, questionnaire, or interview. However, changes in anorectal physiological assessment (e.g., anal pressure, sensory threshold) often do not correlate with symptom relief (i.e., clinical outcomes).

### FECAL INCONTINENCE IN ADULTS

#### Systematic Reviews

A 2014 Cochrane SR of RCTs compared one method of biofeedback to sham-biofeedback, no treatment, or another method of biofeedback in adults (> 18 years of age) with chronic idiopathic (functional) constipation.<sup>[56]</sup> Seventeen RCTs (25 individual reports) were included (N=931); biofeedback was compared to conventional nonsurgical treatment in 7 studies<sup>[57-63]</sup>, to different methods of biofeedback in six studies<sup>[64-69]</sup>, to surgical intervention in two studies<sup>[70, 71]</sup>, to sham treatment in one study<sup>[72]</sup> and to electrical stimulation in one crossover study<sup>[73, 74]</sup>. No studies compared biofeedback to no treatment. Meta-analysis was not possible due to between-study heterogeneity and evidence was rated as low or very low quality due poor methodological quality with high risk of bias. The length of follow-up was determined to be inadequate in many RCTs. There was significant heterogeneity between groups and between studies that precluded meta-analysis. These included between-group differences at baseline, between-study differences in symptoms measured, symptom measurement tools used, and difference in protocols for biofeedback including the type of biofeedback, the number, frequency, and duration of sessions, and patient education (e.g., diet, normal bowel function, lifestyle advice). In addition, the review noted that many of the included RCTs were likely to be underpowered to detect between-group differences. The authors concluded that there is insufficient evidence to allow conclusions on the efficacy and safety of biofeedback for chronic constipation.

This Cochrane SR also reviewed four prior SRs<sup>[75-78]</sup> of RCTs that included systematic literature searches. The review reported methodological limitations in all four of these SRs including incomplete reporting of review methods, limited or non-comprehensive literature search strategies, failure to exclude non-SRs, and meta-analyses of heterogeneous studies. These reviews all reported generally poor quality evidence and the need for further research.

A 2013 SR by Vonthein et al. identified 13 RCTs on biofeedback, electrical stimulation, or the combination for treatment of fecal incontinence.<sup>[79]</sup> Ten RCTs included comparisons of biofeedback and an alternative treatment; some of the biofeedback interventions also involved other components such as sensory training and pelvic floor exercises. A meta-analysis of studies comparing biofeedback to a control intervention significantly favored biofeedback (relative risk, 2.12; 95% CI, 1.42 to 3.16). This study did not attempt to isolate the effect of biofeedback in multicomponent interventions that included pelvic floor exercise or other treatments.

In 2012, an updated Cochrane SR of randomized and quasi-randomized trials for biofeedback and/or sphincter exercises for the treatment of fecal incontinence in adults was published.<sup>[80]</sup> Almost half of the 21 trials were considered low risk for bias. Due to the variety of different treatment combinations, treatment delivery techniques, and outcome measures, comparison between studies was difficult. In addition, most studies reported immediate post-treatment outcomes with follow-up of only a few weeks. The authors reached the following conclusions:

- Biofeedback or electrical stimulation “may offer an advantage over exercises alone” in patients who have failed conservative management (e.g., diet changes, medications).
- Biofeedback following surgical sphincter repair does not improve health outcomes.
- The evidence does not permit conclusions about best practices in the clinical setting, including but not limited to the technique for biofeedback delivery and which patients are suitable for and most likely to benefit from biofeedback.
- Biofeedback is unlikely to cause harm as no study has reported any adverse events or worsening of symptoms.

- There is a need for large, long-term, well-designed RCTs that use validated outcome measures to compare outcomes of biofeedback with other treatments.

## **Randomized Controlled Trials**

One new RCT was published after the above SRs. Damon randomized 157 patients with fecal incontinence to either a treatment group (n=77) receiving perineal retraining including biofeedback and standard conservative treatment, or a control group (n=80) receiving standard conservative treatment.<sup>[81]</sup> This RCT reported only short-term outcomes, with a follow-up of four months. The perineal retraining group had a significantly higher success rate than the control group for daily stool frequency, leakage, and urgency (57% versus 37%, respectively;  $p < 0.021$ ). However, there was no significant difference in quality of life scores between the two groups.

## **FECAL INCONTINENCE IN CHILDREN**

### **Systematic Reviews**

A 2011 updated Cochrane SR<sup>[82]</sup> combined the results of nine trials that compared conventional treatment (i.e., laxatives, toilet training, and dietary advice) with versus without biofeedback in children with fecal incontinence.<sup>[83-91]</sup> The majority of the trials included fewer than 50 participants. Pooling of data was difficult due to the variety of outcome measures; the only outcome reported by all nine trials was the number of children not cured or improved. Combined results of nine trials showed higher rather than lower rates of persisting symptoms of fecal incontinence up to 12 months when biofeedback was added to conventional treatment. In addition, any short-term benefit from biofeedback training did not correspond with later treatment success. The authors concluded that there is no evidence that biofeedback training added any benefit to conventional treatment in the management of functional fecal incontinence in children.

These results confirm the conclusions of prior versions of this Cochrane SR and other SRs.<sup>[92-94]</sup>

### **Randomized Controlled Trials**

Since the above SRs, one additional randomized trial was published in which the authors reported that the results at six-months follow-up did not differ between biofeedback and customary care.<sup>[83]</sup>

## **CONSTIPATION IN ADULTS**

### **Systematic Review**

For the treatment of constipation, a SR of 11 RCTs found a benefit of biofeedback as a treatment of constipation in adults.<sup>[75]</sup> Conclusions of the SR were limited by variability in patient populations, comparison treatments, and outcomes measures. However, detailed examination of several well-conducted RCTs focusing on patients with dyssynergia-type constipation suggested benefits in a sub-group of patients who met criteria similar to trial participants.<sup>[58, 59, 72]</sup> Studies for other types of constipation were limited to poorly-designed RCTs and case series. These unreliable studies do not permit conclusions on the effect of biofeedback on other types of constipation in adults.

## Randomized Controlled Trials

Hart (2012) published an RCT that studied anorectal biofeedback (AB) for constipation. Twenty-one patients with pelvic floor dyssynergia were randomized into two groups.<sup>[59]</sup> One group learned to isolate the anal sphincter using an electromyography probe and the other learned to relax trapezius or temporalis muscles with EMG feedback. The authors concluded that although the sample size was statistically underpowered, AB produced clinical improvements in the severity of constipation. The authors also noted there were several study limitations, including patient selection and long-term follow-up; thus, the evaluation of long-term effects on health outcomes needs to be determined in future studies.

## CONSTIPATION IN CHILDREN

### Systematic Reviews

A systematic review conducted by Wegh (2021) assessed the effectiveness of nonpharmacological interventions for functional constipation in children.<sup>[95]</sup> Studies included in the review were RCTs that enrolled children aged 0 to 18 years with functional constipation as defined by Rome III or IV criteria and reported defecation outcomes and/or QOL outcomes. The review included three RCTs comparing biofeedback alone with biofeedback in conjunction with laxative use. The trials were all assessed as having a high risk of bias. Meta-analysis found no difference between groups in study-defined treatment success (risk difference, 0.23; 95% CI, -0.08 to 0.54) and heterogeneity was high ( $I^2=86\%$ ). Other clinical outcomes and harms of treatment were not reported.

### Randomized Controlled Trials

A RCT conducted by Van Ginkel (2001) evaluated biofeedback in the treatment of constipation in children.<sup>[96]</sup> Groups included standard treatment i.e., education, laxatives (n=111) or standard treatment plus two sessions of anorectal manometry (n=91). Manometry measurements were viewed by the child and parent during measurement sessions and the data discussed after each session with instructions in home exercises. At six weeks follow-up, there was no significant difference in success between the standard treatment group (4%) and the biofeedback group (7%). At the final 104 week follow-up, 43% of the standard treatment group and 35% of the biofeedback group were considered treatment successes. This difference was not significant. The authors noted that 30% of the randomized patients were missing at the final follow-up.

### Section Summary

The current evidence from several well-designed, well-conducted RCTs is sufficient to determine that biofeedback as a treatment of dyssynergia-type constipation may be beneficial in adult patients who meet the policy criteria.

The evidence base is insufficient to draw conclusions or demonstrate a significant health benefit as a result of biofeedback treatments for the treatment of incontinence or constipation other than dyssynergia-type constipation in adults. The evidence is limited to data from studies with significant methodological limitations including inadequate randomization, lack of a placebo control group, heterogeneity between patient groups and between study protocols, and short-term follow-up periods.

## TENSION AND MIGRAINE HEADACHE

### Systematic Reviews

Sullivan (2016) published a SR to evaluate the outcomes of psychological interventions, one of which was biofeedback for migraines.<sup>[97]</sup> Twenty-four studies were reviewed. The authors noted there were methodological limitations from the study review and that biofeedback was not superior to relaxation training or cognitive behavioral therapy.

A number of other SRs, including two Cochrane SRs, have reported small beneficial effects in children and medium to large beneficial effects in adults when biofeedback is used in conjunction with other prevention measures such as relaxation techniques.<sup>[15, 98-104]</sup>

### Randomized Controlled Trials

Despite the poor quality of case series and RCTs, biofeedback has evolved into a standard of care as part of comprehensive regimens, including medication and relaxation techniques, for treatment and prevention of tension-type headaches, and the prevention of migraine headaches.

Data from case series and RCTs is difficult to interpret due to poor study design, high drop-out rates, and inconsistent outcomes.<sup>[105-110]</sup>

### OTHER HEADACHE

The evidence is insufficient to determine the effect of biofeedback for the prevention or treatment of headaches other than migraine and tension headaches, including but not limited to cluster headaches.

### SECTION SUMMARY

Despite the poor quality of studies, biofeedback has evolved into a standard of care as part of comprehensive regimens, including medication and relaxation techniques, for treatment and prevention of tension-type headaches and the prevention of migraine headaches.

There is not enough research to show that biofeedback improves outcomes in patients with headaches other than migraine and tension headaches.

## HYPERTENSION

### SYSTEMATIC REVIEWS

Nagele (2014) published a SR with meta-analysis on stress-reduction techniques in adults with essential hypertension.<sup>[111]</sup> The review included SRs and RCTs with a no-treatment control group and at least 24 weeks follow-up that were published through September 2012. Outcomes of interest were mortality, cardiovascular morbidity/mortality, end-stage renal disease, health related quality of life, adverse events, change in blood pressure, and changes in antihypertensive medication. Biofeedback was one of a number of the stress-reduction techniques included in the review. The review found that data were not reported for most of the patient-relevant outcomes. No benefit was found for use of antihypertensives. Some beneficial effect was found for lowering blood pressure; however, studies were limited by methodological limitations such as heterogeneity between studies, short-term follow-up. The authors



concluded that a beneficial effect of stress-reduction techniques on hypertension remains unproven.

In a 2010 SR, Greenhalgh concluded, "...we found no convincing evidence that consistently demonstrates the effectiveness of the use of any particular biofeedback treatment in the control of essential hypertension when compared with pharmacotherapy, placebo, no intervention or other behavioral therapies."<sup>[112]</sup> Trials generally had small sample sizes; only four included more than 100 patients. Trials included a variety of biofeedback techniques, and some included more than one modality. Results were not pooled due to differences in interventions and outcomes and the generally poor quality of the studies. Only one trial was identified that compared a biofeedback combination intervention to sham biofeedback, and this study did not find a significant difference in the efficacy of the two interventions. Only four studies on biofeedback alone and four on a combined biofeedback intervention reported data beyond six months; most of these found no significant differences in efficacy between the biofeedback and control groups.

Rainforth reviewed RCTs and all previous meta-analyses related to stress reduction programs including biofeedback.<sup>[113]</sup> Each type of therapy was analyzed separately. No significant reduction in blood pressure was achieved using biofeedback alone or biofeedback combined with relaxation training.

## **RANDOMIZED CONTROLLED TRIALS**

Wang (2016) published an RCT evaluating the effect of direct blood pressure biofeedback on patients with prehypertension or stage I hypertension.<sup>[114]</sup> A trained nurse instructed patients in blood pressure self-regulation by using slow diaphragmatic breathing and passive attitude. During the eight-week training (one session per week), patients in the treatment group received real-time blood pressure feedback signals (n=29) and controls received pseudo-feedback signals (n=28). Outcomes were systolic and diastolic blood pressure, measured at baseline and one and eight weeks after training. Both groups significantly decreased blood pressure following training. The decreases were equal in magnitude, suggesting that blood pressure self-regulation training can effectively lower blood pressure, regardless of the type of feedback signal.

Landman (2013) conducted a randomized, double-blind, sham-controlled trial comparing the effects on blood pressure of lowering breathing frequency in patients with type two diabetes and hypertension using active (n=21) and sham (n=24) biofeedback.<sup>[115]</sup> The changes in systolic blood pressure from baseline favored the control group while differences in diastolic blood pressure favored the intervention group. However, these differences from baseline, and the differences between the two groups were not statistically significant.

## **SECTION SUMMARY**

Although there are RCTs evaluating biofeedback for treating hypertension, evidence is insufficient due to the shortage of studies isolating the effect of biofeedback, the generally poor quality of the trials, and the variability among interventions.

## **INSOMNIA**

### **SYSTEMATIC REVIEWS**

No SRs were identified using biofeedback for the treatment of insomnia.

## **RANDOMIZED CONTROLLED TRIALS**

No RCTs were identified using biofeedback for the treatment of insomnia.

## **MOTOR FUNCTION AFTER STROKE, INJURY, OR LOWER LIMB SURGERY**

### **SYSTEMATIC REVIEWS**

Several SRs have been published; none of these conducted quantitative pooling of results due to heterogeneity among study populations, interventions, and outcome measures.

#### **Knee Injury**

A 2010 SR by Silkman evaluated the effectiveness of electromyography (EMG) biofeedback for improving muscle function during knee rehabilitation after injury.<sup>[116]</sup> Four RCTs that compared knee rehabilitation exercise programs with and without biofeedback were identified. Sample sizes in individual studies ranged from 26 to 60 patients. Two of the four studies found a statistically significantly greater benefit in the programs that included biofeedback, and the other two did not find a significant difference between groups. The positive studies assessed intermediate outcomes e.g., contraction values of the quadriceps muscles. None of the studies were designed to assess functional outcomes.

#### **Post-Stroke Motor Function**

Stanton (2017) updated a SR published in 2011 which evaluated the effect of biofeedback on lower-limb activities in patients who have had a stroke.<sup>[117]</sup> Only high-quality RCTs or quasi-RCTs with Physiotherapy Evidence Database (PEDro) scores greater than four were included. The literature search, conducted through September 2015, identified 18 trials (total N=429 patients) for inclusion. Training activities were walking (nine trials), standing (eight trials), and standing up (one trial). Trials were small, with study populations ranging from 12 to 50 patients. Biofeedback techniques included weight distribution from a force platform or sensor (11 trials), muscle activity from EMG (three trials), linear gait parameters (three trials), and joint angle from a goniometer (one trial). Visual feedback was used in seven trials, auditory in seven trials, and a combination of visual/auditory in four trials. Pooled standardized mean difference of the short-term effect of biofeedback from 17 trials (n=417) was significant (0.50; 95% confidence interval [CI], 0.3 to 0.7). Long-term effects could not be calculated because only four trials provided that information.

Stanton (2011) conducted a SR with meta-analysis of RCTs evaluating biofeedback to improve activities involving lower limb function after stroke.<sup>[118]</sup> A total of 22 trials with 591 participants met inclusion criteria. All of the trials had relatively small sample sizes; the largest trial had 54 participants and 15 trials had 30 or fewer participants. The majority of trials (n=17) compared biofeedback plus usual therapy to usual therapy alone. The specific interventions varied; the types of biofeedback included biofeedback of ground reaction force from a force platform with visual and/or auditory feedback (13 trials), muscle activity via visual and/or auditory feedback (five trials), joint position from an electrogoniometer via visual and/or auditory feedback (three trials), and limb position via auditory feedback one trial). The duration of interventions ranged from two to eight weeks, and intensity ranged between one to five days per week.

A pooled analysis of data from 17 trials on short-term effect (i.e. one month or less) found that biofeedback significantly improved lower limb activities compared to usual care or placebo (standardized mean difference [SMD]: 0.41; 95% CI: 0.21 to 0.62). Outcomes included

activities such as directional control during standing, weight distribution between the lower limbs, and gait parameters such as stride length. There was heterogeneity among studies. Trials did not report functional outcomes such as ability to perform activities of daily living (ADL). A sensitivity analysis determined that the heterogeneity was best explained by study quality. When lower quality trials were excluded, biofeedback was still found to improve lower limb activity compared to control conditions (SMD: 0.49, 95% CI: 0.22 to 0.75). A sub-group analysis was also done by type of activity. There was only one high-quality trial on standing up (n=40). A pooled analysis of five high-quality trials on short-term effect found that biofeedback significantly improved standing outcomes compared to control (SMD: 0.42, 95% CI: 0.05 to 0.78). A pooled analysis of four short-term trials on walking also found better outcomes with biofeedback compared to control (SMD: 0.57, 95% CI: 0.10 to 1.03). Five high-quality trials with a total sample size of 136 contributed data to an analysis of long-term term efficacy i.e., one-five months after cessation of the intervention. In this pooled analysis, biofeedback was found to improve outcomes compared to control (SMD: 0.41, 95% CI: 0.06 to 0.75).

A Cochrane SR that assessed EMG biofeedback for the recovery of motor function after stroke was published in 2007.<sup>[119]</sup> It included 13 randomized or quasi-randomized studies with a total of 269 patients. All of the trials compared EMG biofeedback plus standard physiotherapy to standard physiotherapy; in addition to standard physiotherapy, several studies also included a sham biofeedback group. The studies tended to be small and poorly designed. The authors did not find support for EMG biofeedback to improve motor power, functional recovery, or gait quality when compared to physiotherapy alone.

A 2010 SR by Zijlstra searched for studies evaluating biofeedback-based training to improve mobility and balance in adults older than 60 years of age.<sup>[120]</sup> Although the review was not limited to studies on motor function after stroke, more than half of the studies included older adults post-stroke. For inclusion in this review, studies needed to include a control group of patients who did not receive biofeedback and to assess at least one objective outcome measure. A total of 97 potentially relevant articles were identified, and 21 (22%) studies, including 17 RCTs, met the selection criteria. Twelve of the 21 (57%) studies included individuals post-stroke; three included older adults who had lower-limb surgery and six included frail older adults without a specific medical condition. Individual studies were small with sample sizes that ranged from five to thirty patients. The added benefit of using biofeedback could be evaluated in 13 of 21 (62%) studies. Nine of the 13 studies found a significantly greater benefit with interventions that used biofeedback compared to control interventions. However, the outcomes assessed were generally not clinical outcomes but were laboratory-based measures related to executing a task, e.g., moving from sitting to standing in a laboratory setting and platform-based measures of postural sway. The applicability of improvements in these types of measures to clinical outcomes such as the ability to perform activities of daily living or the rate of falls is unknown. Only one study cited in this review reported an improvement in fall rates, and this trial could not isolate the effect of biofeedback from other components of treatment. In addition, only three studies reported long-term outcomes, and none of these reported a significant effect of biofeedback. Conclusions about the efficacy of biofeedback for improving mobility and balance in older adults cannot be drawn from these data due to the lack of evidence on clinical outcomes. Other methodologic limitations included limited data on the durability of effects and the inability to isolate the effect of biofeedback in many studies.

## **RANDOMIZED CONTROLLED TRIALS**

Kim (2017) published a RCT on the effect of EMG on upper-extremity functions in patients who have had a stroke.<sup>[121]</sup> Patients were randomized to traditional rehabilitation therapy (n=15) or traditional rehabilitation therapy plus EMG biofeedback training (n=15). Upper-limb function was measured by Fugl-Meyer Assessment (FMA) and Manual Function Test (MFT), and activities of daily living were measured using the FIM instrument. Both FMA and MFT scores improved significantly more in the patients receiving EMG biofeedback. However, there was not a significant difference in functional independence measurement (FIM) score improvement between groups.

Yang (2016) published a limited in size RCT on the effect of biofeedback weight-bearing training on the ability to sit/stand/sit and on stability among patients who have had a stroke.<sup>[122]</sup> Patients were randomized to biofeedback weight-bearing training (n=15) or functional weight-bearing training (n=15). Outcomes were time to sit/stand/sit and stability (measured by BioRescue, which detects an area of center of pressure). Comparison statistics were calculated for pre- and post training results, and between treatment groups. Both outcomes significantly improved in the biofeedback group but not in the control group.

Ghomashchi (2016) published a RCT evaluating the effect of visual biofeedback on postural balance disorders in patients who have had a stroke.<sup>[123]</sup> Patients received conventional physical therapy and balance training exercises. During balance training, 16 patients were randomized to visual biofeedback and 15 patients to no visual information. Outcomes were the center of pressure and approximate entropy. Both groups experienced improvements in postural control, with no significant differences between rehabilitation methods.

In a small RCT published after the above SR, Barcala randomized 20 adults with hemiplegia following stroke to balance training with visual biofeedback or to conventional physical therapy alone.<sup>[124]</sup> Patients received interventions twice a week for five weeks. Both groups demonstrated significant improvement, but no statistically significant differences were found between the two groups.

## **SECTION SUMMARY**

The evidence on biofeedback for improving motor function after stroke is limited by small studies, most of which are methodologically limited. There is variability in the type, duration, and intensity of interventions. Conclusions about the efficacy of biofeedback for improving mobility and balance in older adults cannot be drawn from the current evidence base.

## **MOVEMENT DISORDERS**

### **SYSTEMATIC REVIEWS**

A Cochrane SR assessing EMG biofeedback for the recovery of motor function after stroke included thirteen randomized or quasi-randomized studies.<sup>[119]</sup> The authors reported that EMG biofeedback did not improve motor power, functional recovery, or gait quality when compared to physiotherapy alone, although the results were limited due to small, poorly designed trials. Use of different assessment scales made pooling data for meta-analysis impossible.

### **RANDOMIZED CONTROLLED TRIALS**

No RCTs identified after the above SR.

## **SECTION SUMMARY**

The current evidence base is insufficient to draw conclusions regarding the role of biofeedback for the treatment of movement disorders.

## MULTIPLE SCLEROSIS

### SYSTEMIC REVIEWS

No SRs were identified for biofeedback for the treatment of multiple sclerosis.

### RANDOMIZED CONTROLLED TRIAL

van der Logt (2016) published a crossover study that evaluated the effect of vibrotactile biofeedback for trunk sway on balance control in patients with multiple sclerosis.<sup>[125]</sup> Ten patients performed a series of stance and gait tasks while trunk sway was measured using a SwayStar device attached to the waist. Patients underwent the series of tasks with and without an add-on to the SwayStar device, which provided patients with direction-specific vibrotactile feedback during the tasks. When patients performed the tasks with vibrotactile biofeedback, there was a general reduction in trunk sway, though not all the reductions differed significantly with trunk sway when performing the tasks without vibrotactile biofeedback. Studies with larger sample sizes are needed.

A 2015, MacKay published results from an (RCT) that evaluated the addition of biofeedback to standard care in 40 patients with relapsing-remitting multiple sclerosis patients to help improve emotional symptoms, coping, and fatigue in patients with multiple sclerosis.<sup>[126]</sup> The standard care psychosocial intervention consisted of relaxation, mindfulness, social support, and education. All patients attended a one-hour training and assessment sessions at weekly intervals. During the first session, all patients had training in mindfulness breathing exercises and progressive muscle relaxation techniques. Patients randomized to the biofeedback arm received additional instruction on use of biofeedback equipment for self-regulation. Following the 3 weekly sessions, patients were instructed to practice the exercises at home, with or without use of biofeedback equipment. Outcomes included breathing rate and anxiety, depression, fatigue, and muscle tension measures. At the end of treatment, there were not statistically significant differences between groups in any outcomes. However, some variables were marginally significant. The difference between the intervention and control group in breathing rate was 3.06 (95% CI, -0.17 to 6.280;  $p=0.06$ ) and the difference in muscle tension was -13.91 (95% CI, -30.06 to 2.25;  $p=0.09$ ). This study is limited by the small sample size, and other methodological constraints that make it hard to determine the efficacy of biofeedback for anxiety, fatigue, and stress in patients with multiple sclerosis.

### SECTION SUMMARY

There is not enough research to show that biofeedback improves health outcomes for the treatment of multiple sclerosis. Additional well-designed, comparative studies are needed.

## ORTHOSTATIC HYPOTENSION IN PATIENTS WITH A SPINAL CORD INJURY

### SYSTEMATIC REVIEW

Gillis conducted a SR to identify and describe the body of literature pertaining to nonpharmacologic management of orthostatic hypotension during the early rehabilitation of persons with a spinal cord injury.<sup>[127]</sup> Participants with any level or degree of completeness of

spinal cord injury and any time elapsed since their injuries were included. Interventions must have measured at least systolic blood pressure and have induced orthostatic stress in a controlled manner and have attempted to control orthostatic hypotension during an orthostatic challenge. Four distinct nonpharmacologic interventions for orthostatic hypotension were identified: application of compression and pressure to the abdominal region and/or legs, upper body exercise, functional electrical stimulation applied to the legs, and biofeedback. Methodologic quality varied dramatically between studies. The authors concluded that "...The clinical usefulness of compression/pressure, upper body exercise and biofeedback for treating OH [orthostatic hypotension] has not been proven."

## **RANDOMIZED CONTROLLED TRIALS**

No RCTs identified after the above SR.

## **SECTION SUMMARY**

There is insufficient evidence from high-quality comparative studies to permit conclusions about the impact of biofeedback on orthostatic hypotension in patients with a spinal cord injury.

## **PRETERM BIRTH PREVENTION**

### **SYSTEMATIC REVIEWS**

No SRs were identified for biofeedback used to prevent preterm birth.

### **RANDOMIZED CONTROLLED TRIALS**

In 2014, Siepmann published data on 48 women who had experienced threatened preterm labor between the 24th and 32nd gestational week.<sup>[128]</sup> Twenty-four patients received six biofeedback sessions over two weeks, and the other 24 patients were in a usual care group. Preterm delivery occurred in three patients (13%) in the biofeedback group and eight patients (33%) in the control group; the difference between groups was not statistically significant ( $p>0.05$ ). Other gestational outcome data, such as the gestational duration and birthweight, also did not differ significantly between groups.

### **SECTION SUMMARY**

There is insufficient evidence that biofeedback is effective in preventing preterm birth in pregnant women with a history of threatened preterm labor.

## **RAYNAUD'S PHENOMENON**

### **SYSTEMATIC REVIEWS**

No SRs were identified for biofeedback for Raynaud's phenomenon.

### **RANDOMIZED CONTROLLED TRIALS**

The Raynaud's Treatment Study Investigators conducted a randomized comparison of sustained-release nifedipine and thermal biofeedback in 313 patients with primary Raynaud's phenomenon.<sup>[129]</sup> In addition to these two treatment groups, there were two control treatments: pill placebo and EMG biofeedback. EMG biofeedback was chosen as a control because it did not address the physiological mechanism of Raynaud's phenomenon. Nifedipine significantly



reduced Raynaud's attacks compared with placebo pill ( $p < 0.001$ ), but thermal biofeedback did not differ from EMG biofeedback ( $p = 0.37$ ). Better outcome for nifedipine relative to thermal biofeedback was nearly significant ( $p = 0.08$ ). With a larger sample size, the rate of 56% fewer attacks with nifedipine relative to thermal biofeedback would likely have been statistically significant. Thus, it cannot be concluded that thermal biofeedback is as effective as this form of medical therapy.

A 2009 SR identified five RCTs that reported a variety of outcomes. A pooled analysis from four RCTs (total  $n = 110$ ) on the change in frequency of attacks favored the sham control group over the biofeedback group.<sup>[130]</sup>

## **SECTION SUMMARY**

There is insufficient evidence from a small number of RCTs that biofeedback is effective as a treatment of Raynaud's disease. A meta-analysis of the available RCTs did not find that biofeedback was more effective than the control intervention.

## **STRESS REDUCTION**

### **SYSTEMIC REVIEWS**

No SRs were identified for biofeedback for stress reduction.

### **RANDOMIZED CONTROLLED TRIALS**

A 2015 Van der Zwan published an RCT comparing the efficacy of self-help physical activity (PA), mindfulness meditation (MM), and heart rate variability biofeedback (HRV-BF) in reducing stress and its related symptoms.<sup>[131]</sup> This study, which was limited in size and objective outcomes indicated that all interventions were equally effective in reducing stress and its related symptoms. The current evidence base is insufficient to permit conclusions on the impact of biofeedback on stress reduction.

## **SECTION SUMMARY**

There is not enough research to show that biofeedback improves health outcomes for stress reduction. Additional well-designed, comparative studies are needed.

## **TINNITUS**

### **SYSTEMATIC REVIEWS**

No SRs were identified for biofeedback for tinnitus.

### **RANDOMIZED CONTROLLED TRIALS**

Weise investigated the efficacy of a biofeedback-based cognitive-behavioral treatment for tinnitus in Germany. Tinnitus patients ( $n = 130$ ) were randomly assigned to an intervention or a wait-list control group.<sup>[132]</sup> Treatment consisted of 12 sessions of a biofeedback-based behavioral intervention over a three-month period. The primary outcome measures were global tinnitus annoyance and a daily rating of tinnitus disturbance measured by a Tinnitus Questionnaire (TQ) and a daily diary using visual analog scale (VAS) scores. Patients in the wait-list group participated in the treatment after the intervention group had completed the treatment. Results showed improvements regarding the following: tinnitus annoyance; diary

ratings of loudness; feelings of controllability; changes in coping cognitions; changes in depressive symptoms; TQ: total score (range 0–84) pre-assessment mean 54.7, post-assessment mean 32.52; TQ: emotional distress (range 0–24) pre-assessment mean 16.00, post-assessment mean 8.15; and diary: loudness VAS (range 0–10) pre-assessment mean 5.68, post-assessment mean 4.38. Improvements were maintained over a six-month follow-up period in which variable effect sizes were observed. The study did not investigate the possible additive effect of biofeedback with cognitive-behavioral therapy and did not include an active treatment control group.

## SECTION SUMMARY

The current evidence base is insufficient to draw conclusions regarding the role of biofeedback for the treatment of tinnitus.

## URINARY DISORDERS

### POST-PROSTATECTOMY URINARY INCONTINENCE

#### Systematic Reviews

Hsu (2016) published a SR evaluating pelvic floor muscle training (PFMT) with biofeedback in men who had radical prostatectomy.<sup>[133]</sup> Thirteen trials met reviewers' inclusion criteria. However, on closer inspection, not all trials included a biofeedback intervention, and other trials did not compare PFMT alone to PFMT plus biofeedback. Thus, conclusions about the added efficacy of biofeedback cannot be determined from the results of this SR.

In 2015 a Cochrane SR was conducted by Anderson to determine the effectiveness of conservative management interventions for urinary incontinence in men after a prostatectomy, which updated the 2012 review by Campbell et al.<sup>[134, 135]</sup> Conservative therapies include pelvic floor muscle training with or without feedback, electrical stimulation, extra-corporeal magnetic innervation, compression devices, lifestyle changes, or a combination of methods. Fifty randomized and quasi-Rs were included in the review; however, just eight of these trials examined biofeedback compared to pelvic floor muscle training. Per the rating of moderate quality studies, the authors found no evidence that pelvic floor muscle training with or without biofeedback was better than control for men who had urinary incontinence up to 12 months after radical prostatectomy.

A SR of PMFT to improve post-prostatectomy urinary incontinence identified three studies (281 men) that focused on the incremental value of biofeedback over written/verbal PME.<sup>[136]</sup> Although PPMFT appeared to reduce the time to recover continence compared to no training, there was no evidence for an advantage of training with biofeedback over written/verbal instructions. None of the individual trials found a statistically significant difference in outcomes between groups.

A 2003 randomized trial by Wille randomized 139 men prior to radical prostatectomy to one of three groups.<sup>[137]</sup> Group one received verbal and written instructions about PFMT from a physical therapist. Group two received PFMT instruction and instruction on using an electrical stimulation device. Group three received the previous two intervention components and training on using biofeedback with the electrical stimulation device. Patients had regular contact with a health care provider for the first five weeks after surgery. In the immediate postsurgical period, 20.5% in group one, 22.9% in group two, and 20.7% in group three were

continent ( $p=0.815$ ). After six and 12 months, continence rates remained similar among the groups. Twelve-month continence rates were 88% in group one, 81% in group two, and 88.6% in group three ( $p=0.524$ ).

Bales (2000) randomized 100 men scheduled to undergo radical prostatectomy to PFMT plus biofeedback intervention ( $n=50$ ) or to a control group ( $n=50$ ) that received written and brief verbal instructions performing PFMT [138]. The intervention consisted of a single session with a trained nurse two to four weeks before surgery. Three men dropped out of the PFMT plus intervention group. At six months after surgery, the incidence of urinary incontinence was 94% (44/47) in the PFMT plus biofeedback group and 96% (948/40) in the control group. The difference between groups was not statistically significant.

## Randomized Controlled Trials

Oh (2020) randomized 84 patients undergoing robot-assisted laparoscopic radical prostatectomy to receive biofeedback with an extracorporeal perineometer plus PFMT or PFMT alone. [139] Although the average urine loss volume was lower in the biofeedback plus PFMT group compared to PFMT alone at month 1 after catheter removal ( $p=0.028$ ), there was no difference between groups at months 2 or 3 after catheter removal. At study end (month 3), the percentage of continent patients was not significantly different between the biofeedback plus PFMT group (67.5%) and PFMT alone (61.9%).

A 2013 trial by Dijkstra-Eshuis compared the impact of preoperative pelvic floor muscle training (PFMT) with biofeedback ( $n=65$ ) to standard care ( $n=56$ ) on postoperative SUI in men undergoing laparoscopic radical prostatectomy. [140] Patients in the intervention group received four weekly sessions of biofeedback-assisted muscle training before surgery. Patients assigned to the control group did not have a presurgical intervention. The primary outcome was the rate of continence one year after surgery. Among the 74 patients available for follow-up analysis, 66% in the intervention group and 80% in the control group were continent at one year. The investigators originally planned to enroll 248 patients. However, an interim analysis after 122 patients were enrolled showed no significant benefit for the intervention group, even if the trial was completed as planned and therefore the trial was halted prematurely.

In 2012, Tienforti compared biofeedback (a session before and after surgery) in combination with written/verbal instructions on performing pelvic floor muscle exercises to a control intervention of written/verbal instructions alone. [141] The study included 34 patients, 32 of whom (16 in each group) were available for the final 6-month analysis. By six months, 10 of 16 patients (62.5%) in the treatment group and one of sixteen patients (6.3%) in the control group had achieved continence; this difference was statistically significant ( $p$  value not reported). The mean number of incontinence episodes per week was also significantly lower in the intervention group (2.7) than the control group (13.1) at six months.

## STRESS, URGE OR MIXED URINARY INCONTINENCE

### Systematic Reviews

Zhu (2022) performed a meta-analysis of 17 RCTs in postpartum women with lower urinary tract symptoms. [142] Fifteen studies ( $n=1965$ ) compared PMFT plus biofeedback and electrical stimulation with PMFT alone. The analysis reported a significantly greater likelihood of achieving a therapeutic effect with combined PFMT plus biofeedback and electrical stimulation versus PMFT alone (risk ratio, 1.20; 95% confidence interval [CI], 1.15 to 1.24;  $I^2=0\%$ ). Pelvic floor muscle strength was also significantly higher with combination therapy ( $p<0.0001$ ), but

there was high heterogeneity among studies for this outcome ( $I^2=66\%$ ). Limitations of this analysis include risk of bias, lack of blinding, and heterogeneity in the definition of therapeutic effect.

Wu (2021) conducted a meta-analysis (N=21 studies; 13 RCTs, 8 nonrandomized) of PMFT with biofeedback versus PMFT alone in women with stress incontinence or pelvic floor dysfunction.<sup>[143]</sup> Most studies were conducted in China and none were from the U.S. There was a significant benefit of PMFT with biofeedback compared to PMFT alone in patients with both urinary incontinence (odds ratio, 4.82; 95% CI, 2.21 to 10.51;  $I^2=85.3\%$ ; n=11 studies) and pelvic floor dysfunction (odds ratio, 2.81; 95% CI, 2.04 to 3.86;  $I^2=13.1\%$ ; n=6 studies). Analyses of quality of life and quality of sexual life results were limited by substantial heterogeneity (>80%). Limitations of this analysis include an unclear, moderate, or high risk of bias in all studies and use of Kegel exercises only in some studies rather than a complete PMFT program.

An updated Agency for Healthcare Research and Quality (AHRQ) SR and comparative effectiveness report of nonsurgical treatments for urinary incontinence in women was published by Blak (2018).<sup>[144]</sup> Biofeedback was considered among nonpharmacological behavioral therapy approaches. The report evaluated 42 studies that compared 19 active nonpharmacological interventions (including combinations of nonpharmacological interventions) with each other. One study reported statistically significant improvements in the daily activities domain with PFMT and biofeedback compared with PFMT alone, and one study reported significant improvements in distress for bladder training combined with PFMT and biofeedback when compared to bladder training, however, nine studies either reported discordant or nonsignificant differences across all other domains for this comparison. No adverse events were reported for any of the studies evaluating biofeedback. The report concludes that behavioral therapy, alone or in combination with other interventions, is generally more effective than other first- and second-line interventions alone for both stress and urgency UI.

A SR by Mateus-Vasconcelos (2018) assessed various physiotherapy methods to strengthen the pelvic floor muscles for women with stress urinary incontinence.<sup>[145]</sup> Their review included six studies which were RCTs, quasi-experimental trials, and systematic reviews. One study (an uncontrolled RCT) included biofeedback as a comparator; the effectiveness of pelvic floor muscle training (PFMT) with biofeedback (group n=6) to PFMT with palpation (group n=5) was evaluated. The exercises for the biofeedback group consisted of achieving the same number of rapid and slow contractions of the same duration as that achieved during the PERFECT scheme (8 series). The palpation group strengthened the pelvic floor muscles while a physiotherapist performed palpations on the central perineal tendon and vagina (4 sessions). At the end of treatment, there was no statistical difference in improvement between the biofeedback group and the palpation group in power, endurance, or rapidity of contractions. This RCT was limited in its small sample size and lack of control group and masking of assessors.

Oliveira (2017) published a SR that evaluated the protocols and/or PFMT parameters for women with stress urinary incontinence.<sup>[146]</sup> Seven studies were included, two of which involved biofeedback. The authors concluded that strengthening exercises for pelvic floor training combined with biofeedback was the most effective training protocol, but because of the limited studies and heterogeneity of the intervention protocols they could not identify what the most effective training protocol would be.

Moroni (2016) published a SR of 37 RCTs on conservative treatment of stress urinary incontinence in women.<sup>[147]</sup> Five trials (N=250) were identified that compared PFMT plus biofeedback with biofeedback alone. A pooled analysis of four studies found significantly more urine loss as measured by a posttreatment pad test with PFMT alone than with PFMT plus biofeedback (mean difference [MD], 0.90; 95% confidence interval [CI], 0.71 to 1.10). Reviewers noted that the difference between groups was likely not clinically significant because there was only about a one-gram difference. Moreover, the finding was largely due to the effect of one study. Results on other outcomes (eg, quality of life, number of incontinence episodes) could not be pooled due to imprecision of the estimates.

A 2011 Cochrane SR evaluated feedback or biofeedback in conjunction with pelvic floor muscle training (PFMT) for treating urinary incontinence (UI) in women.<sup>[148]</sup> The review included RCTs in women with stress, urge or mixed UI in which at least two arms of the study included exercise training and at least one arm included feedback and/or biofeedback. Feedback was defined as verbal feedback by a clinician, whereas biofeedback involved use of an instrument or device. After examining 36 full-text articles, 24 trials were found to meet the review's inclusion criteria and 17 contributed data to the analysis of at least one primary outcome measure. Sixteen of the 24 trials included a comparison of PFMT plus biofeedback to PFMT alone; nine of these included the same PFMT programs in both groups. The primary outcomes of the review were quality of life and improvement or cure. Nine trials used one of several validated quality-of-life instruments; however, only four of these reported data in a form that could be used for meta-analysis. Thus, quality-of-life results were not pooled. Data were pooled for the other primary outcome, improvement or cure, but there were a sufficient number of studies only for the comparison between PFMT with and without biofeedback. In a pooled analysis of seven studies, there was a significant reduction in the proportion of women reporting 'no improvement or cure' when biofeedback was added to muscle exercise (risk ratio [RR]: 0.75, confidence interval [CI]: 0.66 to 0.86). The authors noted that there may have been other differences between groups, such as more frequent contact with a healthcare professional or a greater number of treatment sessions, which might partially explain the difference in the improvement or cure rate in women who did or did not receive biofeedback. Moreover, when only the outcome 'no cure' was examined, there was not a significant difference between groups that did and did not receive biofeedback (5 studies: RR: 0.92, 95% CI: 0.81-1.05). Among secondary outcomes, a pooled analysis of seven trials did not find a significant difference in leakage episodes in a 24-hour period after treatment (mean difference: -0.01, 95% CI: -0.21 to 0.01). For the outcomes frequency and nocturia, data could not be combined but the review authors reported that the pattern was one of no difference between groups.

A number of significant design flaws in the 24 trials that met inclusion criteria (N=1583 women) limit the reliability of the reported outcomes. These flaws included:

- It was common for the women in the biofeedback arm to have more contact with healthcare professionals than those who did not receive biofeedback;
- Many of the trials were at moderate to high risk of bias; and
- There was significant variation in the regimens proposed for feedback and biofeedback, and the intervention's purpose and composition were often unclear.

The authors concluded that feedback or biofeedback may provide additional benefit to pelvic floor muscle exercises (PME) alone; however, further research is needed to differentiate

whether the beneficial effect was due to feedback, biofeedback, or some other difference between the trial arms.

## **Randomized Controlled Trials**

Hagen (2020) conducted a multicenter RCT in 600 women with stress or mixed urinary incontinence. Participants were randomized to 16 weeks of PMFT with electromyographic biofeedback or PMFT alone. Both groups received supervised PMFT during clinic appointments and a home PMFT regimen. The mean number of appointments attended was about four in both groups. Urinary incontinence symptoms (self-reported at month 24 via the International Consultation on Incontinence Questionnaire on Urinary Incontinence Short Form [ICIQ-UI-SF]) were similar in both groups (mean difference, -0.09; 95% CI, -0.92 to 0.75;  $p=.84$ ). ICIQ-UI-SF scores were also similar between groups at earlier times (6 and 12 months). At 24 months, the proportion of patients who achieved the study's definition of cure, improvement, and symptoms that were very much better or much better was similar between groups. Pelvic floor muscle strength and endurance was assessed at 6 months, with similar findings in both groups. A limitation of this study is the short duration of the intervention compared to the length of follow-up.

A double-blind, sham-controlled RCT by Terlikowski (2013) compared transvaginal electrical stimulation (TVES) with active ( $n=68$ ) or sham ( $n=34$ ) EMG-biofeedback in premenopausal women with stress urinary incontinence (SUI).<sup>[149]</sup> The group receiving active biofeedback had significantly better results than the sham group for reduction in urinary leakage, pelvic floor muscle strength, and incontinence-related quality of life. No significant between group difference was found in urodynamic data. The authors concluded that TVES with active EMG biofeedback “is a trustworthy method for treating premenopausal women with stress urinary incontinence; however reliability needs to be established.”

Other RCTs comparing the efficacy of PFMT alone with PFMT with biofeedback have been published. Statistically significant differences in outcomes between interventions were not consistently found, however, sample sizes were small (<25 per group) and thus the studies may have been underpowered.

## **VOIDING DYSFUNCTION**

### **Systematic Reviews**

Fazeli published a SR with meta-analysis to better understand how biofeedback has been used to treat children, up to age 18, with symptoms of bladder dysfunction not responding to standard therapy alone.<sup>[150]</sup> Five eligible studies were included in the SR. Four of the studies were pooled in the meta-analysis for a total of 382 participants. The overall proportion of cases with resolved incontinence at six months was similar in biofeedback and control groups (OR 1.37 [95% CI 0.64 to 2.93], RD 0.0.7 [-0.9, 0.23]). There was no significant difference in mean maximum urinary flow rate (mean difference 0.50 ml, range -0.56 to 1.55) or likelihood of urinary tract infection (OR 1.30 [95% CI 0.65 to 2.58]). This SR was limited by the paucity of research, high quality studies, and small sample sizes.

### **Randomized Controlled Trials**

In 2015, Sener published results from a retrospective RCT that compared the outcomes of four biofeedback sessions (group one;  $n=20$ ) with six to ten biofeedback sessions (group two;  $n=20$ ) on treating children with dysfunctional voiding.<sup>[151]</sup> Normalized voiding after the



treatment was determined in 18 subjects from group one, and 19 subjects in group two. Fifteen out of the 40 total study sample were determined to have reflux. At the six month evaluation of group one, voiding dysfunction had resolved in seven, had improved in three, and persisted in one. In group two, voiding dysfunction had resolved in ten, improved in three. This study is limited by a small sample size and other methodological constraints that make it difficult to determine the efficacy of biofeedback for children with dysfunctional voiding.

In 2015, Minardi published results from a four arm RCT to evaluate the therapeutic effects of tamsulosin and biofeedback on recurrent urinary tract infections in 155 women with dysfunctional voiding.<sup>[152]</sup> The study consisted of four groups: group one received uroflowmetry biofeedback, group two received  $\alpha$ 1-adrenoceptor antagonists, group three received uroflowmetry biofeedback combined with  $\alpha$ 1-adrenoceptor antagonists, and group four received no treatment. Patients were evaluated by the American Urological Association Symptom Index. Urodynamics was carried out in patients of groups one, two and three at three, six and 12 months, whereas urodynamics was only carried out at 12 months in group four. The incidence of storage and emptying symptoms, mean post-void residual, mean flow rate, flow time, voiding volume, and urinary tract infections decreased at three, six, and twelve month for all four groups. This study was limited by the small sample size, attrition, and other methodological constraints making it hard to determine the efficacy of biofeedback for women with recurrent urinary tract infections and dysfunctional voiding.

## **OTHER URINARY INCONTINENCE**

### **Systemic Reviews**

No SRs were identified for biofeedback for the treatment of other urinary incontinence.

### **Randomized Control Trials**

An RCT of 74 patients with multiple sclerosis reported that the addition of neuromuscular electrical stimulation with biofeedback training resulted in 85% incontinence reduction, compared to a 47% incontinence reduction in the control group trained only with biofeedback.<sup>[153]</sup>

### **Section Summary**

The available evidence for the use of biofeedback in the treatment of stress and/or or urge urinary incontinence in female patients includes several RCTs and SRs. Although there is some heterogeneity across these studies, there is enough research to show that biofeedback improves outcomes in women with urinary incontinence when administered in conjunction with pelvic floor muscle training (PFMT). The current evidence base is insufficient to draw conclusions regarding the role of biofeedback for the treatment of urinary incontinence other than in this setting.

## **OTHER INDICATIONS**

Other indications for which there are no clinical trial publications sufficient to demonstrate the effectiveness of biofeedback include, but are not limited to the following:

- Cardiovascular disorders
- Chronic fatigue syndrome

- Chronic obstructive pulmonary disease (COPD)
- Epilepsy<sup>[154]</sup>
- Facial palsy
- Hand hemiplegia
- Low vision
- Side-effects of cancer chemotherapy

## PRACTICE GUIDELINE SUMMARY

### **AMERICAN ACADEMY OF SLEEP MEDICINE (AASM)**

In 2008, an AASM special committee released a guideline on evaluation and management of chronic insomnia in adults.<sup>[155]</sup> The AASM considers biofeedback as one of a number of common therapies that are “effective and recommended in the treatment of chronic primary and comorbid (secondary) insomnia (Guideline)” The AASM definition for guideline is “a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level two Evidence (RCTs with high alpha and beta error) or a consensus of Level three Evidence (non-randomized concurrently controlled studies).”

### **AMERICAN COLLEGE OF GASTROENTEROLOGY**

In 2014, the American College of Gastroenterology (ACG) published guidelines on the management of fecal incontinence.<sup>[156]</sup> The guideline indicated that pelvic floor rehabilitation techniques (eg, biofeedback, therapeutic exercises) are effective in patients with fecal incontinence who do not respond to conservative measures (strong recommendation, moderate quality of evidence).

### **AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG)<sup>[157]</sup>**

In 2015 ACOG reaffirmed their 2009 clinical practice guidelines on urinary incontinence in women. Biofeedback was not included in these recommendations.

### **AMERICAN COLLEGE OF PHYSICIANS**

The American College of Physicians published a guideline titled “Noninvasive Treatments for Acute, Subacute, and Chronic Back Pain: a Clinical Practice Guideline From the American College of Physicians”. The guideline stated low quality evidence supports biofeedback for chronic low back pain.

### **AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE (ACOEM)**

In 2020, the ACOEM updated their guideline on noninvasive and minimally invasive management of low back disorders.<sup>[158]</sup> The role of biofeedback is not addressed in this updated guideline.

### **AMERICAN GASTROENTEROLOGICAL ASSOCIATION (AGA)**

The updated AGA position statement (2013) on constipation considers biofeedback a possible treatment for patients with dyssynergia-type constipation with severe symptoms and proven

pelvic floor dysfunction “to train patients to relax their pelvic floor muscles during straining and to correlate relaxation and pushing to achieve defecation (Strong Recommendation, High-Quality Evidence).”<sup>[159, 160]</sup>

The following statement on biofeedback was included: “Pelvic floor retraining by biofeedback therapy rather than laxatives is recommended for defecatory disorders (Strong Recommendation, High-Quality Evidence).”

### **AMERICAN HEART ASSOCIATION**

A 2013 the American Heart Association published a statement based on a systematic literature review on alternatives to diet and medication for lowering blood pressure (BP) in patients with hypertension.<sup>[161]</sup> The report found meta-analyses to have had mixed results, though some recent trials showed reduction in BP with certain biofeedback techniques. However, recommendations for any specific techniques could not be made due to the paucity of data. The statement recommended that biofeedback could be considered for treatment of hypertension. This recommendation was rated as Class IIB, Level of Evidence B recommendation, defined as usefulness/efficacy less well-defined based on conflicting evidence from a single RCT or nonrandomized studies; additional studies with broad objectives needed.

### **AMERICAN NEUROGASTROENTEROLOGY AND MOTILITY SOCIETY**

In 2015, the American Neurogastroenterology and Motility Society and the European Society of Neurogastroenterology and Mobility jointly published consensus-based guidelines on biofeedback therapy for anorectal disorders.<sup>[162]</sup> The guidelines included the following recommendations:

- “Biofeedback is recommended for the short-term and long-term treatment of constipation with dyssynergic defecation.”
- “Biofeedback therapy is recommended for the short-term and long-term treatment of fecal incontinence”
- “Biofeedback therapy is not recommended for the routine treatment of children with functional constipation, with or without overflow fecal incontinence.”

### **AMERICAN SOCIETY OF COLON AND RECTAL SURGEONS (ASCRS)**

In 2016, ASCRS published guidelines on the evaluation and management of constipation.<sup>[163]</sup> The guideline states that biofeedback therapy is a first-line treatment for symptomatic pelvic floor dyssynergia (strong recommendation, moderate quality of evidence).

An American Society of Colon and Rectal Surgeons practice parameter recommended biofeedback “as an initial treatment for motivated patients with incontinence with some voluntary sphincter contraction. Biofeedback may be considered a first-line option for many patients with fecal incontinence who have not responded to simple dietary modification or medication. Supportive counseling and practical advice regarding diet and skin care can improve the success of biofeedback. Biofeedback may be considered before attempting sphincter repair or for those who have persistent or recurrent symptoms after sphincter repair. It may have a role in the early postpartum period in females with symptomatic sphincter weakness. Biofeedback and a pelvic floor exercise program can produce improvement that lasts more than two years. Biofeedback home training is an alternative to ambulatory training

programs, especially in the elderly.” The authors assigned a level of evidence of III and grade of recommendation B, defined as well-designed, quasi-experimental nonrandomized studies with generally consistent findings.

### **AMERICAN UROLOGICAL ASSOCIATION AND THE SOCIETY OF URODYNAMICS, FEMALE PELVIC MEDICINE & UROGENITAL RECONSTRUCTION (AUA/SUFU)<sup>[164]</sup>**

The 2014 AUA/SUFU evidence-based practice guidelines recommended offering behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training) as first line therapy to all patients with overactive bladder. This recommendation was rated as a Standard, defined as a directive statement that an action should or should not be taken. The strength of evidence was rated as Grade B (moderate quality; moderate certainty). Biofeedback was included among a number of other modalities as a component of behavioral therapies. The guideline reported that the limited literature did not show any single component of behavioral therapy to be essential to efficacy or to be superior in efficacy.

### **TENSION AND MIGRAINE HEADACHES**

Clinical practice guidelines from professional associations include biofeedback in their recommendations for prevention of tension and migraine headaches.<sup>[165-168]</sup> The associations included the American Academy of Neurology, the National Institute of Neurologic Disorders and Stroke, the U.S. Headache Consortium, and the European Federation of Neurological Societies.

### **NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE**

In 2017, the National Institute for Clinical Excellence (NICE) issued evidence-based guidance on constipation in children and young people, which was reaffirmed in 2014.<sup>[169]</sup> The guidance indicated that biofeedback should not be used for ongoing treatment.

## **SUMMARY**

It appears that biofeedback may improve health outcomes for some people for prevention of tension-type and migraine headaches. Clinical guidelines based on research recommend biofeedback for people with tension and migraine headaches. Therefore, biofeedback may be considered medically necessary when policy criteria are met.

There is enough research to show that biofeedback improves health outcomes for people with dyssynergia-type constipation. Clinical guidelines based on research recommend biofeedback for pelvic floor training for dyssynergia constipation in adults. Therefore, biofeedback may be considered medically necessary when policy criteria are met.

There is enough research to show that biofeedback improves outcomes in individuals with stress and/or urge urinary incontinence when administered in conjunction with pelvic floor muscle training (PFMT). Clinical practice guidelines recommended behavioral therapies including biofeedback as to patients with overactive bladder. Therefore, biofeedback may be considered medically necessary in individuals with stress and/or urge urinary incontinence when administered in conjunction with pelvic floor muscle training (PFMT).

There is not enough research to show that biofeedback improves health outcomes for people with the variety of investigational indications listed in the criteria. In addition, no

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clinical guidelines based on research recommend biofeedback for these indications. Therefore, biofeedback is considered investigational for all other indications.

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## CODES

Codes	Number	Description
CPT	90875-90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying, or supportive psychotherapy); code range
	90901	Biofeedback training by any modality
	90911	Biofeedback training, perineal muscles, anorectal, or urethral sphincter, including EMG and/or manometry
HCPCS	E0746	Electromyography (EMG), biofeedback device
ICD-10-PCS	GZC9ZZZ	Mental health, biofeedback, other biofeedback

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