Medical Policy

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***Current Policy Effective Date: 5/1/25**
(See policy history boxes for previous effective dates)

Title: Biofeedback

Description/Background

Biofeedback is a technique intended to teach patients the self-regulation of certain unconscious or involuntary physiologic processes. The technique involves the feedback of a variety of types of information not usually available to the patient, followed by a concerted effort on the part of the patient to use this feedback to help alter the physiologic process in a specific way.

Biofeedback has been proposed as a treatment for a variety of diseases and disorders including, but not limited to, anxiety, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud disease, and insomnia. The type of feedback used in an intervention (e.g., visual, auditory) depends on the nature of the disease or disorder being treated.

Regulatory Status

A large number of biofeedback devices have been cleared through the U.S. Food and Drug Administration's 510(k) process.

Medical Policy Statement

Biofeedback have been established. It may be considered a useful therapeutic option for patients meeting selection criteria.

Inclusionary and Exclusionary Guidelines

Inclusions:

- The treatment of stress and/or urge urinary incontinence in cognitively intact adults who have failed a documented trial of pelvic muscle exercise (PME) training. A failed trial of PME training is defined as no clinically significant improvement in urinary incontinence after completing four weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.
- For children with daytime urinary dysfunction when the child meets the following criteria:
  - Ages four years or older
  - Neurologic, anatomic, infectious or functional causes have been ruled out
  - Able to comprehend and follow verbal instructions
- Biofeedback for fecal incontinence or constipation is indicated for those who are motivated, and mentally capable. Patients must have some degree of rectal sensation and be able to contract the external anal sphincter.
- Biofeedback for migraine and tension-type headache when used as part of the overall treatment plan.

Exclusions:

- Cluster headaches
- Chronic pain
- Hypertension
- Stroke
- All other conditions not noted in the inclusionary guidelines

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

90901 90912 90913

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Urinary Incontinence

Several methodologic difficulties arise in assessing biofeedback.[1] 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 some studies have reported a beneficial effect of multimodality treatment, without appropriate control conditions, it is impossible to isolate the specific contribution of biofeedback to the overall treatment effect. For example, relaxation, attention, or suggestion may account for successful results that have been attributed to biofeedback. These are nonspecific therapeutic factors, some of which can be considered placebo effects. To demonstrate efficacy

of biofeedback for treating incontinence, studies are needed to isolate the effect of biofeedback and demonstrate an improvement in health outcomes compared with other interventions (e.g., relaxation or behavioral therapy alone). In addition, although research has shown that feedback on physiologic processes has enhanced patients' ability to control these processes, evidence is needed on the relationship between a patient's ability to exert control over the targeted physiologic process and any health benefits of the intervention. The latter finding underscores the importance of seeking controlled studies showing whether the use of biofeedback improves disease-related health outcomes, as opposed to physiologic, intermediate outcomes.

WOMEN WITH URINARY INCONTINENCE

Clinical Context and Therapy Purpose

The purpose of biofeedback with pelvic floor muscle training (PFMT) in women who have urinary incontinence is to provide a treatment option that is an alternative to or an improvement in existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is women with urinary incontinence.

Urinary incontinence is a common condition defined as involuntary leakage of urine. Women are twice as likely to be affected as men, and prevalence increases with age. The severity of incontinence affects the quality of life and treatment decisions. The types of urinary incontinence women may experience include stress, urge, overflow, and functional. Nonsurgical treatment options may include pharmacologic treatment, pelvic muscle exercises, bladder training exercises, electrical stimulation, and neuromodulation.

Interventions

The therapy being considered is biofeedback with PFMT.

Comparators

The following therapy is currently being used to make decisions about urinary incontinence: PFMT without biofeedback.

Outcomes

The general outcomes of interest are symptom improvement (e.g., incontinence episodes) and functional improvement (generally 1 to 4 treatments per week, for 8 to 12 weeks).[2] Outcome measures for women with urinary incontinence are listed in Table 1.

Table 1. Outcomes Measures for Women with Urinary Incontinence

Measure	Outcome Evaluated	Description	Follow-up Timing
Oxford Grading Scale Pelvic Floor Muscle Function	Functional improvement	Used by physiotherapists to assess muscle strength as graded 0 to 5.[3,] 0 = no movement 1 = flicker of movement 2 = through full range actively with gravity counterbalanced 3 = through full range actively against gravity 4 = through full range actively against some resistance 5 = through full range actively against strong resistance	Baseline and at end of therapy (8-12 weeks)
PERFECT Scheme	Functional improvement	A way of measuring pelvic muscle function and strength. PERFECT stands for[4,] **P**ower (Modified Oxford Scale) **E**ndurance (how long contraction is held, up to 10 s) **R**epetitions (up to 10 repetitions of a 10-s hold) **F**ast (number of 1-s contractions in a row, up to 10) **E**very **c**ontraction **T**imed (reminder to time every contraction)	Baseline and at end of therapy (8-12 weeks)
Urogenital Distress Inventory (UDI-6)	Lower urinary tract symptoms	6-item questionnaire assessing:[25,] Urination frequency Urine leakage related to urgency Urine leakage related to physical activity Small amounts of urine leakage Difficulty with bladder emptying Lower abdomen or genitalia discomfort Scored on a 0-100 point scale.	NR

s: second(s)

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews

Zhu et al (2022) performed a meta-analysis of 17 RCTs in postpartum women with lower urinary tract symptoms.[5] Fifteen studies (N=1965) compared PFMT plus biofeedback and electrical stimulation with PFMT alone. The analysis reported a significantly greater likelihood of achieving a therapeutic effect with combined PFMT plus biofeedback and electrical stimulation versus PFMT alone (risk ratio, 1.20; 95% confidence interval [CI], 1.15 to 1.24; I2=0%). Pelvic floor muscle strength was also significantly higher with combination therapy (p<.0001), but there was high heterogeneity among studies for this outcome (I2=66%). Limitations of this analysis include that 6 studies had a high risk of bias, no studies were blinded, there was evidence of publication bias, most studies were conducted in China, and the study's definition of therapeutic effect was not clearly stated.

Wu et al (2021) conducted a meta-analysis (N=21 studies; 13 RCTs, 8 nonrandomized) of PFMT with electromyographic biofeedback versus PFMT alone in women with stress incontinence or pelvic floor dysfunction.[6] Most studies were conducted in China and none were from the U.S. In an analysis of studies that reported cure and improvement, there was a significant benefit of PFMT with electromyographic biofeedback compared to PFMT alone in patients with both urinary incontinence (odds ratio, 4.82; 95% CI, 2.21 to 10.51; I2=85.3%; n=11 studies) and pelvic floor dysfunction (odds ratio, 2.81; 95% CI, 2.04 to 3.86; I2=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 PFMT program.

In their systematic review, Mateus-Vasconcelos et al (2018) assessed various physiotherapy methods to strengthen the pelvic floor muscles for women with stress urinary incontinence.[7] Their review included a mix of RCTs, quasi-experimental trials, and systematic reviews—a total of six studies. Only one study (an uncontrolled RCT) included biofeedback a comparator. That study (Pinheiro et al, [2012]) compared the effectiveness of PFMT with biofeedback (group n=6) to PFMT with palpation (group n=5). 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 (eight series).[8] The palpation group strengthened the pelvic floor muscles while a physiotherapist performed palpations on the central perineal tendon and vagina (four 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.

Moroni et al (2016) published a systematic review of 37 randomized controlled trials (RCTs) on conservative treatment of stress urinary incontinence in women.[9] Five trials (N=250) were identified that compared pelvic floor muscle training (PFMT) plus biofeedback with biofeedback alone; the studies included a total of 250 women. A pooled analysis of 4 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 1-gram difference. Moreover, the finding was largely due to the effect of 1 study. Results on other outcomes (e.g., QOL, number of incontinence episodes) could not be pooled due to imprecision of the estimates.

In an Agency for Healthcare Research and Quality comparative effectiveness review, Shamliyan et al (2012) identified 6 RCTs (N=542) comparing PFMT plus biofeedback with

PFMT alone.[10] A meta-analysis of these studies did not find a statistically significant difference between interventions in continence rates. When findings were pooled, the relative risk (RR) was 1.27 (95% CI, 0.88 to 1.85). The absolute risk difference was 0.08 (95% CI, -0.03 to 0.19).

In a Cochrane systematic review, Herderschee et al (2011) assessed RCTs on feedback or biofeedback in conjunction with PFMT for treating urinary incontinence in women.[11] 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 met reviewers' eligibility criteria, and 17 contributed data to the analysis of at least 1 primary outcome measure. Sixteen of the 24 trials compared PFMT plus biofeedback with PFMT alone; 9 of them included the same PFMT programs in both groups. The primary outcomes of the review were QOL and improvement or cure. Nine trials used one of several validated quality-of-life instruments; however, only 4 of these reported data in a form amenable to 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 7 studies, there was a significant reduction in the proportion of women reporting "no improvement or cure" when biofeedback was added to muscle exercise (RR=0.75; 95% CI, 0.66 to 0.86). Reviewers noted there may have been other differences between groups, such as more frequent contact with a health care professional or a greater number of treatment sessions, which might partially explain the difference between the improvement or cure rates in women who did or did not receive biofeedback. Moreover, when only the outcome "no cure" was examined, there was no significant difference between groups that did and did not receive biofeedback (5 studies; RR=0.92; 95% CI, 0.81 to 1.05). Among secondary outcomes, a pooled analysis of 7 trials did not find a significant difference in leakage episodes in a 24-hour period after treatment (MD = -0.01; 95% CI, -0.21 to 0.01). For the outcomes frequency and nocturia, data could not be combined but reviewers reported that the pattern was one of no difference between groups.

Randomized Controlled Trials

Selected larger RCTs that compared PFMT with and without biofeedback are summarized in this section. Hagen et al (2020) conducted a multicenter RCT in 600 women with stress or mixed urinary incontinence.[12] Participants were randomized to 16 weeks of PFMT with electromyographic biofeedback or PFMT alone. Both groups received supervised PFMT during clinic appointments and a home PFMT regimen. The mean number of appointments attended was about 4 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). The 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.

Williams et al (2006) published a study that included 238 women who had failed a primary behavioral therapy (e.g., advice on fluid intake, bladder reeducation, weight loss) for 3 months.[13] They were randomized to intensive PFMT (n=79), PFMT using vaginal cones (n=80), or continued behavioral therapy (n=79) for 3 months. Patients in all 3 groups were seen in the clinic every other week for 8 weeks and at 12 weeks. At 12 weeks, all 3 groups had moderate reductions in incontinence episodes and some improvement in voiding frequency; there were no statistically significant differences in outcomes among the 3 groups. For

example, mean reduction in incontinence episodes over 24 hours was -1.03 in the PFMT group, -0.28 in the vaginal cone group, and -0.59 in the control group (p=.2).

Burgio et al (2002) reported on findings of an RCT with 222 women who had the urge or mixed incontinence.[2] Interventions in this 3-armed trial were as follows: (1) 74 patients who received behavioral training along with digital palpation instruction (no biofeedback) and 4 office visits in 8 weeks; (2) 73 patients who received biofeedback-assisted behavioral training and 4 office visits in 8 weeks; and (3) 75 patients who were given a self-help book with no office visits (control condition). Behavioral training in the two intervention groups included teaching pelvic floor exercises as well as skills and strategies for reducing incontinence. Patients in all groups kept bladder diaries through the eight-week treatment period. In an intention-to-treat analysis, the mean reduction in incontinence episodes was 69.4% in the behavioral training plus verbal feedback group, 63.1% in the behavioral training plus biofeedback group, and 58.6% in the control group. The 3 groups did not differ significantly from one another (p=.23). In addition, QOL outcomes were similar in the three groups.

Other RCTs comparing the efficacy of PFMT alone with PFMT with biofeedback have been published.[14,15] They tended not to find statistically significant differences in outcomes between interventions; however, sample sizes were small (i.e., <25 per group) and thus the studies may have been underpowered.

Section Summary: Women with Urinary Incontinence
Numerous RCTs have evaluated biofeedback as a treatment of urinary incontinence in women. Trial reporting methodologies varied, and many did not isolate the potential contribution of biofeedback. A comparative effectiveness review did not find a statistically significant difference in continence rates when patients received PFMT with or without biofeedback. Other systematic reviews evaluating biofeedback and/or verbal feedback as part of treatment for urinary incontinence found improvement in some outcomes (e.g., improvement or cure, urine volume) but not others (e.g., cure, leakage episodes).

Men with Prostatectomy-related Urinary Incontinence

Clinical Context and Therapy Purpose
The purpose of biofeedback with PFMT in men who have post-prostatectomy urinary incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is men with post-prostatectomy urinary incontinence.

Interventions
The therapy being considered is biofeedback with PFMT.

Comparators
The following therapy is currently being used to make decisions about urinary incontinence: PFMT without biofeedback.

Outcomes

The general outcomes of interest are symptom reduction and functional outcomes (approximately eight weeks).[16]

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Hsu et al (2016) published a systematic review of PFMT with biofeedback in men who had a radical prostatectomy.[17] Thirteen trials met reviewers' inclusion criteria. However, on 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 meta-analysis.

A Cochrane review by Johnson et al (2023) assessed conservative treatments for post-prostatectomy urinary incontinence.[18] Reviewers included a comparison of PFMT (with or without biofeedback) and sham or no treatment. The authors did not evaluate the potential incremental value of biofeedback (i.e., by comparing PFMT with biofeedback and PFMT without biofeedback).

Previously, MacDonald et al (2007) conducted a systematic review of PFMT to improve urinary incontinence after radical prostatectomy.[19] Reviewers identified 3 studies (281 men) that compared biofeedback and PFMT with muscle training alone (written/verbal instructions provided). Study findings were not pooled; none of the individual trials included in the review found a statistically significant difference in outcomes between groups.

Randomized Controlled Trials
Goode et al (2011) reported on a RCT evaluating biofeedback and PFMT in 208 men with urinary incontinence persisting at least 1 year after radical prostatectomy.[16] Men with pre-prostatectomy incontinence were excluded. Participants were randomized to 1 of 3 groups: 8 weeks of behavioral therapy (PFMT and bladder control exercises; n=70), behavioral therapy plus biofeedback and electric stimulation (n=70), and a delayed-treatment control group (n=68). The biofeedback and electric stimulation intervention, called "behavior-plus," consisted of in-office electric stimulation with biofeedback using an anal probe and daily home pelvic floor electrical stimulation. After 8 weeks, patients in the 2 active treatment groups were given instructions for a maintenance program of pelvic floor exercises and fluid control and were assessed at 6 and 12 months. The primary efficacy outcome was reduction in the number of incontinent episodes at eight weeks, as measured by a seven-day bladder diary. A total of 176 (85%) of 208 randomized men completed the 8 weeks of treatment. In an intention-to-treat analysis of the primary outcome, the mean reduction in incontinent episodes was 55% (28 to13 episodes/week) in the behavioral therapy group, 51% (26 to12 episodes/week) in the behavior-plus group, and 24% (25 to 20 episodes/week) in the control group. The overall difference between groups was statistically significant (p=.001), but the behavior plus intervention did not result in a significantly better outcome than behavioral therapy alone. Findings were similar on

other outcomes. For example, at the end of 8 weeks, there was a significantly higher rate of complete continence in the active treatment groups (11/70 [16%] in the behavior group, 12/70 [17%] in the behavior-plus group) than the control group (4/68 [6%]), but the group receiving biofeedback and electrical stimulation did not have a significantly higher continence rate than the group receiving behavioral therapy alone.

Section Summary: Post-Prostatectomy Urinary Incontinence
An RCT and systematic reviews have evaluated the efficacy of biofeedback with PFMT for treatment of prostatectomy-related urinary incontinence compared with PFMT without biofeedback. Results of these data mixed and have not consistently reported significantly improved outcomes with biofeedback added to the intervention. The timing and delivery of the intervention were not well-defined. Systematic reviews have not pooled study findings.

Planned Radical Prostatectomy

Clinical Context and Therapy Purpose
The purpose of biofeedback with PFMT in men who are scheduled for radical prostatectomy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is men scheduled for radical prostatectomy.

Interventions
The therapy being considered is biofeedback with PFMT.

Comparators
The following therapy is currently being used to make decisions about urinary incontinence: PFMT without biofeedback.

Outcomes
The general outcomes of interest are symptom prevention and functional outcomes (starting two to four weeks before the procedure and continuing after; follow-up three to twelve months).[20, 21, 22, 23]

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

Several trials have evaluated the use of pre- or perioperative biofeedback for patients undergoing radical prostatectomy for prevention of postoperative urinary incontinence. Oh et al (2020) randomized 84 patients undergoing robot-assisted laparoscopic radical prostatectomy to receive biofeedback with an extracorporeal perineometer plus PFMT or PFMT alone. [20] 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%).

Tienforti et al (2012) reported on a RCT comparing biofeedback (sessions before and after surgery) in combination pelvic floor muscle exercises with a control intervention PFMT alone in patients undergoing radical prostatectomy.[21] The trial enrolled 34 patients, 32 of whom (16 in each group) were available for the final 6-month analysis. By 6 months, 10 (62.5%) of 16 patients in the treatment group and 1 (6.3%) of 16 patients in the control group were continent (p=.002). The mean number of incontinence episodes per week was also significantly lower in the intervention group (2.7) than in the control group (13.1) at 6 months (p=.005).

A trial by Wille et al (2003) randomized 139 men prior to radical prostatectomy to 1 of 3 groups.[22] Group 1 received verbal and written instructions about PFMT from a physical therapist. Group 2 received PFMT instruction and instruction on using an electrical stimulation device. Group 3 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 1, 22.9% in group 2, and 20.7% in group 3 were continent (p=.815). After 6 and 12 months, continence rates remained similar among the groups. Twelve-month continence rates were 88% in group 1, 81% in group 2, and 88.6% in group 3 (p=.524).

Bales et al (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. [23] 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 6 months after surgery, there was no difference between groups; incidence of urinary incontinence was 94% (44/47) in the PFMT plus biofeedback group and 96% (948/40) in the control group.

Tables 2 and 3 more fully summarize key trial characteristics and results of these trials.

Table 2. Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	***Comparator***

Oh et al (2020)[20]	South Korea	1	2015-2017	84 patients undergoing robot-assisted laparoscopic radical prostatectomy	Biofeedback (using extracorporeal device [Anykegel]) and PFMT after catheter removal (n=42)	PFMT after catheter removal (n=42)
Tienforti et al (2012)[21]	Italy	1	2009-2010	38 patients who underwent standard open retropubic radical prostatectomy for prostate cancer	Biofeedback (using anal probe [PelveenCare]) after catheter removal and PFMT (n=16)	Verbal and written instructions on PFMT to be performed at home (n=16)
Wille et al (2003)[22]	Germany	1	1999-2001	139 patients who underwent radical retropubic prostatectomy	Biofeedback (using anal probe) plus PFMT and electrical stimulation (n=46)	Comparator 1: Verbal and written instructions about postoperative PFMT with intensive physiotherapy (n=47) Comparator 2: PFMT and electrical stimulation (n=46)
Bales et al (2000)[23]	U.S.	1	NR	100 patients undergoing radical retropubic prostatectomy	Biofeedback and instructions on PFMT (n=50)	Verbal and written instructions on PFMT (n=50)

NR: not reported; PFMT: Pelvic floor muscle training

Table 3. Summary of Key Randomized Controlled Trial Results

Study (Year)	Final N	Continence	Average 24-hour urine loss
Oh et al (2020)[20]		*Loss of 0 g of urine on a 24-h pad test*	
Biofeedback + PFMT	40	27/40 (67.5%) (3 months)	71.0 ± 48.0 g (month 1), 59.7 ± 83.4 g (month 2), 38.8 ± 141.2 g (month 3)
PFMT alone	42	26/42 (61.9%) (3 months)	120.8 ± 132.7 g (month 1), 53.1 ± 96.6 g (month 2), 19.5 ± 57.2 (month 3)
P value		.649	.028 (month 1), 0.744 (month 2), 0.415 (month 3)
Tienforti et al (2012)[21]		*ICIQ-UI score of 0*	
Biofeedback + PFMT	16	6/16 (month 1), 8/16 (month 2), 10/16 (month 3)	NR
PFMT	16	0/16 (month 1), 1/16 (month 2), 1/16 (month 3)	NR
P value		0.02 (month 1), 0.01 (month 2), 0.002 (month 3)	NR

Wille et al (2003)[22]		*Assessed by questionnaire*	*Assessed by 20-minute pad test*[a]	
Biofeedback + PFMT + electrical stimulation	46	20.7% (immediate postsurgical period), 88.6% (12 months)	33% (immediate postsurgical), 90.5% (12 months)	NR
PFMT+ electrical stimulation	46	22.9% (immediate postsurgical period), 81% (12 months)	36.4% (immediate postsurgical), 82% (12 months)	NR
PFMT	47	20.5% (immediate postsurgical period), 88% (12 months)	29% (immediate postsurgical), 76.7% (12 months)	NR
P value		.815 (immediate postsurgical), 0.524 (12 months)	.822 (immediate postsurgical), 0.236 (12 months)	NR
Bales et al (2000)[23]		*Use of 1 or less pad per day*		
Biofeedback + PFMT	47	44/47 (94%) (6 months)		NR
PFMT	50	48/50 (96%) (6 months)		NR
P value		.596		NR

[a] The 20-minute pad test assesses continence by performing various activities with a bladder volume of 75% while wearing a pad to collect urine. ICIQ-UI: International Consultation on Incontinence Questionnaire on Urinary Incontinence; NR: not reported; PFMT: pelvic floor muscle training.

Tables 4 and 5 display notable limitations in the trials. Major limitations include a limited number of outcomes assessed by trials (e.g., not including safety data), an inability to blind patients and/or the outcome assessment due to the nature of the intervention, unclear methods of allocation concealment, and missing power calculations. Although most studies did not include safety endpoints, biofeedback is generally considered a safe treatment.[18]

Table 4. Study Relevance Limitations

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-up[e]
Oh et al (2020)[20]				1. Key health outcomes not addressed; 3. Incomplete reporting of harms	

Tienforti et al (2012)[21.]			3. Delivery not similar intensity as intervention		
Wille et al (2003)[22.]				1. Key health outcomes not addressed; 3. Incomplete reporting of harms;	
Bales et al (2000)[23.]			3. Delivery not similar intensity as intervention	1. Key health outcomes not addressed; 3. Incomplete reporting of harms;	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study; Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Oh et al (2020)[20.]		1. Not blinded to treatment assignment; 2. Not blinded outcome assessment				
Tienforti et al (2012)[21.]		1. Not blinded to treatment assignment				
Wille et al (2003)[22.]	3. Allocation concealment unclear	1. Not blinded to treatment assignment; 2. Not blinded outcome assessment			1. Power calculations not reported	
Bales et al (2000)[23.]	3. Allocation concealment unclear	1. Not blinded to treatment assignment			1. Power calculations not reported	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Section Summary: Men Scheduled for Radical Prostatectomy

RCTs have evaluated the efficacy of biofeedback with PFMT for prevention of prostatectomy-related urinary incontinence compared with PFMT without biofeedback. These trials generally reported poor outcomes with biofeedback added to the intervention. The timing and delivery of the intervention were not well-defined.

Summary of Evidence: Urinary Incontinence

For individuals who have urinary incontinence (women) who receive biofeedback with pelvic floor muscle training (PFMT), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. A comparative effectiveness review did not find a statistically significant difference in continence rates when patients received PFMT with or without biofeedback. Other systematic reviews evaluating biofeedback and/or verbal feedback as part of treatment for urinary incontinence found improvement in some outcomes, but not others.

For individuals who have post-prostatectomy urinary incontinence or who are scheduled for radical prostatectomy who receive biofeedback with PFMT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Results of these data were mixed, and did not consistently report significantly improved outcomes when biofeedback was added to the intervention. The timing and delivery of the intervention were not well-defined. Additional well-designed trials are needed that demonstrate the superiority of biofeedback with PFMT over PFMT alone.

For individuals who will undergo radical prostatectomy, the evidence includes RCTs that have evaluated the efficacy of biofeedback with PFMT compared with PFMT without biofeedback for prevention of prostatectomy-related urinary incontinence. These trials generally reported poor outcomes with biofeedback added to the intervention. The timing and delivery of the intervention were not well-defined.

There is lack of data evaluating biofeedback for individuals who are unable to undergo PFMT or who fail treatment with PFMT. Studies on biofeedback demonstrate improvement in symptoms of urinary incontinence and results are fairly comparable to those achieved with PFMT, therefore the addition of biofeedback to the therapeutic regime may be useful for in patients who fail other treatments.

Daytime Urinary Dysfunction in Children

A synthesis of the evidence on management of bladder dysfunction in children (UpToDate 2024) states, “biofeedback is reserved for children with bladder and sphincter dyssynergia that is contributing to persistent daytime incontinence despite an adequate trial of conservative therapy and/or pharmacotherapy.” The publication notes that data on effective treatment of bladder dysfunction in children is limited due to flaws in study design. However, “several

observational studies in children report that biofeedback therapy appears to reduce symptoms associated with bladder dysfunction and decrease postvoid residual volumes."[24]

Fecal Incontinence

The purpose of biofeedback in individuals who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant populations of interest are individuals with fecal incontinence.

Interventions

The therapy being considered is biofeedback. Biofeedback teaches individuals self-regulation of certain physiologic processes not normally considered to be under voluntary control. Biofeedback attempts to improve rectal sensory perception, strength, coordination, or some combination of these three components.

Biofeedback training for fecal incontinence focuses on improving the ability to voluntarily contract the external anal sphincter and puborectalis muscles in response to rectal filling and to decrease the delay in response to a sensation of distension.

Comparators

The comparators of interest are medical management and sphincteroplasty. Medical management consists of bulking agents and anti-diarrheal agents. If anti-diarrheal agents are ineffective, bile acid binders may be recommended. Sphincteroplasty, which is recommended when conservative therapies have failed, involves the surgical reconstruction of a sphincter muscle.

Outcomes

The relevant clinical outcome for biofeedback as a treatment for incontinence should be an overall change in an individual's symptoms. Reduction in episodes of fecal incontinence and increase in voluntary bowel movements are the primary clinical outcomes, and these are typically reported as the percentage of individuals cured or improved. Achieving normal defecation dynamics (e.g., anal pressure, squeeze pressure, sensory threshold, rectal inhibitory reflex, defecation dynamics) does not correspond with symptom relief (i.e., clinical outcomes). Anorectal physiology measurements are a poor proxy for changes in clinical symptoms. Individual symptoms are usually assessed through a diary, questionnaire, or interview (completed by the affected individual and, in the case of children, parents).

Biofeedback training may take several weeks. Follow-up occurs after training and should continue for several months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Adults

Systematic Reviews

Several systematic reviews of RCTs on biofeedback treatment for fecal incontinence in adults have been published. A systematic review by Vonthein et al (2013) identified 13 RCTs on biofeedback, electrical stimulation, or their combination for the treatment of fecal incontinence.[2] Ten trials compared biofeedback with an alternative treatment; some of the biofeedback interventions involved other components such as sensory training and pelvic floor exercises. A meta-analysis of studies comparing biofeedback with a control intervention significantly favored biofeedback (relative risk, 2.12; 95% confidence interval [CI], 1.42 to 3.16). Reviewers did not isolate the effect of biofeedback in multicomponent interventions that included pelvic floor exercise or other treatments.

A Cochrane review by Norton et al (2012) identified 21 RCTs evaluating biofeedback and/or sphincter exercises for treating fecal incontinence in adults.[3] Most studies used multifaceted interventions (e.g., biofeedback, education, sphincter exercise). Additionally, a wide variety of control interventions were used. Three trials compared biofeedback plus sphincter exercises with sphincter exercises alone, and a single trial compared biofeedback plus four type of exercise with biofeedback plus another type of exercise. Reviewers did not pool study findings due to heterogeneity among trials.

Enck et al (2009) identified 11 RCTs evaluating the efficacy of biofeedback therapy for fecal incontinence in adult populations.[4] Two RCTs were excluded, one because of the small sample size and the other because it did not include an appropriate control group. The remaining nine studies comprised five comparisons of different biofeedback modalities and six comparisons of electromyographic (EMG) biofeedback versus other types of therapy, mainly pelvic floor exercises. (Two studies had multiple treatment groups and were included in both categories.) The total number of patients included in the 9 studies was 540; sample sizes of individual studies ranged from 18 to 171 patients. A meta-analysis of 5 studies did not find a significant difference in the efficacy of different types of biofeedback (pooled odds ratio [OR], 1.23; 95% confidence interval [CI], 0.74 to 2.20; p=.38). Similarly, a meta-analysis of studies comparing biofeedback with other therapies did not find a significant difference in efficacy (pooled OR=1.19; 95% CI, 0.69 to 2.05). The outcome measure used in the analysis was not specified and appeared to vary from study to study.

Randomized Controlled Trials

An RCT published subsequent to the systematic reviews randomized 300 women with fecal incontinence to biofeedback or patient education, plus loperamide or placebo. [5] The primary outcome of the study was change from baseline in St. Mark's Fecal Incontinence severity scale score. A -5 point change in score was determined *a priori* as clinically meaningful. After 24 weeks follow up, there was no statistical or clinical difference in fecal incontinence score between the biofeedback and education groups (mean difference -0.7, 95% confidence interval -2.6 to 1.2; p=.47) or between the biofeedback plus loperamide versus biofeedback plus placebo groups (mean difference -1.9, 95% confidence interval -4.1to 0.3; p=.09). In patient-

reported bowel diaries, the combination of biofeedback plus loperamide was associated with less stool leakage (p=.04) and more continent days per week (p=.03) relative to biofeedback plus placebo.

Heymen et al (2009), included in the Vonthein systematic review, randomly assigned 168 individuals with fecal incontinence to 3 months of biweekly pelvic floor exercise training alone (n=85) or exercise training with manometric biofeedback (n=83).[6] Twenty-two patients in the exercise-only group and 38 in the biofeedback group improved during a 4-week run-in period and did not participate further, leaving 63 in the exercise group and 45 in the biofeedback group. The primary efficacy outcome was decrease in scores on the Fecal Incontinence Severity Instrument, a validated 4-item scale, from the end of run-in to three months. The analysis included all patients who completed at least one treatment (15 patients dropped out). The study reported a greater reduction in Fecal Incontinence Severity Instrument scores in the biofeedback group than in the exercise-only group (p=.01; exact scores were not reported). Complete continence (no staining) was reported by 13 (21%) of 63 patients in the exercise-only group and 20 (44%) of 45 in the biofeedback group; this difference was statistically significant (p=.008). A study limitation was that only 108 (64%) of 168 randomized patients received the intervention and, therefore, baseline imbalances in the treatment groups might have affected study outcomes. A stronger design would be to randomize patients after, not before, a run-in period.

Children

Systematic Reviews

An updated Cochrane review by Brazzelli et al (2011) assessed behavioral and cognitive interventions for children with fecal incontinence.[7] Of 21 included studies, 9 compared conventional treatment alone (i.e., laxatives, toilet training, dietary advice) with conventional treatment plus biofeedback. Eight trials included children with functional fecal incontinence and the ninth included children with fecal incontinence due to myelomeningocele (n=12). Four trials included children who had fecal incontinence due to constipation, and three others included children who had fecal incontinence due to constipation and pelvic floor dyssynergia. When data from the 9 studies were combined, 133 (51%) of 260 children in the conventional treatment plus biofeedback group were not cured or improved at follow-up compared with 121 (48%) of 250 children in the conventional treatment-only group. In a meta-analysis, this difference was not statistically significant (OR=1.08; 95% CI, 0.63 to 1.84). The analysis combined 6- and 12-month follow-up data; 12-month data were used when available. Reviewers concluded that findings from RCTs did not support the claim that biofeedback training provides additional benefit to conventional treatment in the management of fecal incontinence associated with constipation. They also stated that, due to a lack of sufficient trials, they could not evaluate the effects of biofeedback in children with organic fecal incontinence.

Section Summary: Fecal Incontinence

The available evidence on biofeedback for fecal incontinence in adults and children includes RCTs and systematic reviews of those RCTs. Although the studies are characterized by heterogeneity of the interventions, comparators, and follow-up durations used, some studies demonstrated biofeedback was effective in improving symptoms of fecal incontinence. It may be a useful therapeutic option for patients who fail to respond to other treatments.

Constipation, Other Than Dyssynergic Type Constipation

Clinical Context and Therapy Purpose

The purpose of biofeedback in individuals who have constipation other than dyssynergia-type constipation to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with constipation other than dyssynergia-type constipation.

Interventions

The therapy being considered is biofeedback. Biofeedback teaches patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. Biofeedback attempts to improve rectal sensory perception, strength, coordination, or some combination of these 3 components.

Biofeedback aims to teach patients how to tighten and relax their external anal sphincter to facilitate bowel movements.

Comparators

The comparator of interest is medical management, which may consist of fiber supplementation, laxatives, or osmotic agents.

Outcomes

The relevant clinical outcome for biofeedback as a treatment for constipation other than dyssynergia-type constipation is an overall change in patient symptoms. The main clinical outcome is an increase in voluntary bowel movements. Achieving normal defecation dynamics (eg, anal pressure, squeeze pressure, sensory threshold, rectal inhibitory reflex, defecation dynamics) does not correspond with symptom relief (ie, clinical outcomes). Anorectal physiology measurements are a poor proxy for changes in clinical symptoms. Patient symptoms are usually assessed through a diary, questionnaire, or interview (completed by the patient and, in the case of children, parents).

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Adults

Systematic Reviews

Several systematic reviews of RCTs have been published on idiopathic constipation. A Cochrane review by Woodward et al (2014) identified 17 trials (N=931 patients) addressing the efficacy of biofeedback for treating adults with idiopathic constipation.[8] Seven trials compared biofeedback with conventional nonsurgical treatment, six compared alternative approaches with biofeedback, two compared biofeedback with a surgical intervention, one compared biofeedback with electrical stimulation, and one used a sham control. Sample sizes ranged from 21 to 109 patients (mean, 48 patients per trial). Sixteen RCTs were judged to be at high risk of bias due to blinding of patients and outcome assessment. Blinding in the remaining study was unclear. Trials all used different biofeedback protocols and 11 used EMG biofeedback. Length of follow-up varied; four trials followed patients to the end of the intervention and seven trials followed patients for one year. In most trials, a symptom scoring system was used as an outcome, with scores varying by symptoms included. Due to heterogeneity among trials, meta-analyses were not conducted. Reviewers concluded that there was insufficient evidence to draw conclusions about the efficacy of any particular biofeedback protocol used to treat chronic constipation in adults.

The Enck et al (2009) review, discussed in the Fecal Incontinence section, also reviewed the literature on biofeedback for constipation and conducted several meta-analyses.[4] Eight RCTs conducted in adults were identified. Four compared two types of biofeedback; meta-analysis of these four studies did not find a significant benefit for one technique over another (pooled OR=1.44; 95% CI, 0.69 to 3.09; p=.32). The other four studies compared biofeedback with another treatment. Comparison treatments (one study each) were botulinum toxin, laxatives, diazepam, and best supportive care (diet, exercise, laxatives). Two studies also included a third arm, in which treatment was a sham or placebo intervention. Three of the 4 studies included patients with dyssynergia-type constipation, and the fourth included patients with anismus. Meta-analysis of the four studies comparing one treatment with another (using the active intervention arm as the comparator in the three-arm trials) found a significantly greater benefit of biofeedback in improving constipation symptoms (pooled OR=3.23; 95% CI, 1.88 to 5.58; p<.001). Results of this systematic review were limited by heterogeneity in patient populations, comparator treatments, and outcome measures.

Children

Systematic Reviews

Gordon et al (2024) conducted a systematic review of treatments for intractable functional constipation in children.[9] Ten RCTs were included, 6 of which had a high concern for bias. Only one study evaluated biofeedback, and that study was considered a low certainty of evidence due to concern for bias and a small sample size. Symptom resolution was improved with biofeedback compared to no intervention (risk ratio, 2.50; 95% CI, 1.08 to 5.79) but the conclusion of efficacy was uncertain.

A systematic review conducted by Wegh et al. (2021) assessed the effectiveness of nonpharmacological interventions for functional constipation in children.[10] 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 3 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

An RCT conducted by Van Ginkel et al (2001) et al selected 212 Dutch children at least 5 years old with constipation who met at least 2 of the following 4 criteria: (1) stool frequency fewer than 3 times per week; (2) 2 or more soiling and/or encopresis episodes per week; (3) periodic passage of very large amounts of stool every 7 to 30 days; or (4) a palpable abdominal or rectal fecal mass.[11] Participants were randomly assigned to 6 weeks of standard treatment (i.e., education, laxatives [n=111] or standard treatment plus 2 sessions of anorectal manometry (n=91). During the manometry sessions, children were asked to squeeze the sphincter as tightly as possible five times. Squeeze pressure data were digitally converted; data could be viewed on a computer by the child and parent. Data were discussed after the sessions, and instructions were given on how to perform defecation exercises at home. Ten (5%) of 212 randomly assigned patients did not receive treatment; the remainder completed the intervention. Treatment success was defined as achieving three or more bowel movements per week and fewer than one soiling and/or encopresis episodes per two weeks while not receiving laxatives. At 6 weeks, 4 (4%) of 111 in the standard treatment group and 6 (7%) of 91 in the biofeedback group were considered to have successful treatment; this difference was not statistically significant. There was also no statistically significant difference between groups at any other follow-up point. At the final follow-up, 36 (43%) of 83 patients in the standard treatment group and 23 (35%) of 65 in the biofeedback group were considered treatment successes. Data on 30% of randomized patients were missing at final follow-up. This trial did not control for nonspecific effects of biofeedback.

Section Summary: Constipation, Other Than Dyssynergic-Type Constipation

For adults with constipation other than dyssynergic-type, the evidence for biofeedback consists of multiple randomized trials, which have been summarized in several systematic reviews. Although evidence is limited by the heterogeneity of patient populations, comparator groups, and outcome measures, some studies demonstrated improvement in constipation symptoms with biofeedback therapy.

Dyssynergic-Type Constipation

Clinical Context and Therapy Purpose

The purpose of biofeedback in individuals who have dyssynergic-type constipation to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with dyssynergia-type constipation.

Interventions

The therapy being considered is biofeedback. Biofeedback teaches patients self-regulation of certain physiologic processes not normally considered to be under voluntary control.

Biofeedback attempts to improve rectal sensory perception, strength, coordination, or some combination of these 3 components.

Biofeedback aims to teach patients how to tighten and relax their external anal sphincter to facilitate bowel movements.

Comparators
The comparator of interest is medical management, which may consist of fiber supplementation, laxatives, or osmotic agents.

Outcomes
The relevant clinical outcome for biofeedback as a treatment for dyssynergia-type constipation is an overall change in patient symptoms. Increase in voluntary bowel movements is the primary clinical outcome. Achieving normal defecation dynamics (eg, anal pressure, squeeze pressure, sensory threshold, rectal inhibitory reflex, defecation dynamics) does not correspond with symptom relief (ie, clinical outcomes). Anorectal physiology measurements are a poor proxy for changes in clinical symptoms. Patient symptoms are usually assessed through a diary, questionnaire, or interview (completed by the patient and, in the case of children, parents).

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Pun et al (2024) conducted a systematic review and meta-analysis of 10 RCTs that assessed physiotherapy interventions on fecal incontinence following colorectal surgery.[12,] Biofeedback was more effective than usual care in measures of rectal muscle strength (all $p<.05$), and biofeedback combined with pelvic floor muscle training was more effective than pelvic floor training alone (all $p<.05$). The effect of biofeedback on constipation symptoms was not reported. These results are limited by a high risk of bias and heterogeneity of the included trials.

A systematic review of 11 RCTs (N=725) compared biofeedback with various interventions for dyssynergic constipation in adults. [13] Both the Heyman and Rao trials, discussed below, were included in the review. Biofeedback was compared with a variety of interventions, including oral medications, botox injection and sham biofeedback. Pooled evidence from 6 of the trials (including Heyman and Rao) found a significant benefit of biofeedback versus no biofeedback in global clinical improvement (odds ratio 3.63, 95% confidence interval 1.10 to 11.93) but heterogeneity was high (I2=87%). Resolution of dyssynergia favored biofeedback based on pooled evidence from 4 trials, but the risk estimate was very imprecise (odds ratio 9.43, 95%

confidence interval 0.80 to 111.20; I2=93%). Due to variance in reporting, the review did not report pooled estimates for other outcomes.

Randomized Controlled Trials

Heyman et al (2007) assessed adults who met Rome II diagnostic criteria for pelvic floor dyssynergia, had at least 2 symptoms of functional constipation for at least 12 weeks in the past year, and had manometry or EMG findings consistent with chronic constipation (e.g., evidence of inadequate propulsive forces and incomplete evacuation).[14] Patients participated in a four-week run-in period comprising education on diet and exercise and provision of fiber and stool softeners. Those who still met eligibility criteria at the end of the run-in period (84/117 [72%]) were randomly assigned to EMG biofeedback (n=30), diazepam 5 mg (n=30), or placebo medication (n=24). All participants were trained to perform pelvic floor exercises and received 6 biweekly visits over 3 months, each lasting approximately 50 minutes. Patients and investigators were blinded to which patients received active versus placebo medication but not to whether they received biofeedback. In an intention-to-treat (ITT) analysis after the 3-month intervention, the proportion of patients reporting adequate relief of constipation symptoms was 70% in the biofeedback group, 23% in the diazepam group, and 38% in the placebo group; biofeedback had a significantly greater benefit when compared with diazepam (p<.001) or placebo (p<.017). A strength of this study design was its attempt to control for nonspecific effects of biofeedback (e.g., increased contact with a health care provider, lifestyle modification advice), by including a run-in period and similar follow-up visits for all groups. Moreover, randomization did not occur until after the run-in period, so treatment groups were more likely to be similar at the start of the treatment phase.

Rao et al (2007) included patients who met Rome diagnostic criteria for functional constipation, had dyssynergia-type constipation, and, when expelling a simulated stool, had either prolonged difficulty (at least one minute) or prolonged delay (at least 20% marker retention in colonic transfer).[15] All participants had failed the routine management of constipation. Seventy-seven patients were randomly assigned to receive 3 months of one of 3 therapies: education and dietary advice (n=24), standard therapy and biofeedback therapy (n=28), or standard therapy and sham feedback (n=24). Patients receiving active biofeedback received up to six biweekly one-hour sessions: training was performed using a rectal manometry probe and software for displaying biofeedback data. In the sham treatment group, patients also used a rectal manometry probe but did not receive visual and verbal feedback. Patients were not blinded to treatment group, but the manometry reader was unaware of treatment assignment. In ITT analysis, after the 3-month intervention, patients in the biofeedback group reported a significantly greater increase in complete spontaneous bowel movements than the sham feedback group (p<.05) and the standard treatment group (p<.062). Additionally, a greater proportion of patients in the biofeedback group reported improved global bowel satisfaction compared with the sham feedback group (p=.04), but the difference from the standard treatment group was not statistically significant. For primary physiologic parameters, ITT analysis found that the dyssynergia pattern was corrected in 79% of those in the biofeedback group, 4% in the sham group, and 8% in the standard treatment group. This difference was statistically significant in favor of the biofeedback group compared with the other groups (p<.001 for both analyses). Moreover, balloon expulsion time during simulated defecation decreased significantly more in the biofeedback group than in the sham (p=.003) or standard treatment (p=.03) groups (exact times not reported for ITT analysis).

In a follow-up publication, Rao et al reported on 1-year findings for 13 (62%) of 21 patients in the biofeedback group and 13 (57%) of 23 in the standard treatment group.[16] Patients in the

sham group were not included in this follow-up. The extension study included visits at three-month intervals, with additional advice provided as needed. Seven (54%) of the 13 biofeedback patients and all 13 patients in the standard treatment group completed 1-year follow-up. Mean change in complete spontaneous bowel movements (the primary outcome) favored the biofeedback group (increase, 2.9) compared with the standard treatment group (decrease, 0.2). The follow-up study suggested longer term effectiveness of biofeedback for this patient population. Although small numbers of patients who completed one-year follow-up limits conclusions that can be drawn.

Section Summary: Dyssynergic-Type Constipation
For patients with dyssynergic constipation treated with biofeedback, several RCTs and a systematic review have reported improvements in constipation symptoms.

Summary of Evidence: Fecal Incontinence and Constipation
There is evidence in randomized controlled trials (RCTs) and systematic reviews demonstrating biofeedback techniques are safe and effective in the treatment of fecal incontinence, especially for patients who do not respond to conservative treatment.

Evidence for dyssynergia-type constipation treated with biofeedback includes RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, and quality of life (QOL). Several well-conducted RCTs focusing on patients with dyssynergia-type constipation have reported benefits in a subgroup of patients meeting well-defined criteria.

Evidence for constipation other than dyssynergia-type treated with biofeedback includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and QOL. A systematic review of RCTs found a benefit of biofeedback as a treatment for constipation in adults.

Published guidelines and recommendations support biofeedback therapy for the treatment of constipation.

Headache

Migraine and Tension-Type Headache

Clinical Context and Therapy Purpose
The purpose of biofeedback for individuals who have migraines or tension-type headaches is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with migraines or tension-type headaches.

Interventions
The therapy being considered is biofeedback.

Comparators
The following therapy is currently being used to treat migraines or tension-type headaches: standard therapy without biofeedback.

Outcomes
The general outcomes of interest are reductions on instances and intensity of migraines or tension-type headaches and reductions in medication usage. The intent of biofeedback use is for the prevention of migraine or tension-type headache. The American Headache Society[2], identified the following treatment goals of preventive biobehavioral therapy (including biofeedback):

- Reduced frequency and severity of headache;
- Reduced headache-related disability;
- Reduced reliance on poorly tolerated or unwanted pharmacotherapies;
- Enhanced personal control of migraine;
- Reduced headache-related distress and psychological symptoms.

Follow-up over the course of 10 to 20 sessions would be of interest to monitor for outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Adults

Systematic Reviews
Nestoriuc et al (2007, 2008) published systematic reviews on biofeedback for migraines and tension-type headaches.[3,4] Meta-analysis for the treatment of migraine included 55 studies (randomized, pre-post, uncontrolled) with 39 controlled trials, reporting a pooled medium effect size of 0.58 (95% confidence interval [CI], 0.52 to 0.65) for treatment of migraine.[3] Effect sizes were computed using Hedges' g, which quantifies between-group treatment outcome differences (mean difference between groups divided by the pooled standard deviation). For the treatment of tension-type headaches, 53 studies met criteria for analysis; they included controlled studies with standardized treatment outcomes, follow-up of at least 3 months, and at least 4 patients per treatment group.[4] Meta-analysis showed a medium-to-large effect size of 0.73 (95% confidence interval 0.61 to 0.84) that appeared to be stable over 15 months of follow-up. Biofeedback was reported to be more effective than headache monitoring, placebo, and relaxation therapies. Biofeedback in combination with relaxation was more effective than biofeedback alone, and biofeedback alone was more effective than relaxation alone, suggesting different elements for the two therapies. Although these meta-analyses were limited by the inclusion of studies of poor methodologic quality, reviewers did not find evidence of an influence of study quality or publication bias in their findings.

Verhagen et al (2009) conducted a systematic review of behavioral treatments for chronic tension-type headaches in adults.[5] Eleven studies, including two studies with low risk of bias, compared biofeedback with waiting-list conditions. Results were found to be inconsistent due to low power, leading reviewers to conclude that larger and more methodologically robust studies should be performed.

Martino Cinnera et al (2023) conducted a systematic review and meta-analysis of electromyographic biofeedback for headache. A total of 29 RCTs were included in the systematic review, and 4 RCTs were included in the meta-analysis.[6,] The headache types represented in the included studies were tension headache (69%), migraine (30%), and mixed types (1%). Risk of bias was generally low in the included studies, but about 60% of studies had concerns about potential deviations from the intended intervention. There was also high heterogeneity regarding patient demographics. The meta-analysis found no difference in headache frequency (p=.66), intensity (p=.99), or duration (p=.54) between electromyographic biofeedback and controls.

Children and Adolescents

Systematic Reviews
Stubberud et al (2016) reported on a meta-analysis of biofeedback as prophylaxis for pediatric migraine.[7] They identified 5 RCTs (total n=137 children and adolescents) that met inclusion criteria. Mean age among the 5 included RCTs ranged from 10 to 13 years. Meta-analysis found that biofeedback reduced migraine frequency (MD in attacks per week, -1.97 ;95% CI , -2.72 to -1.21; p<.001), attack duration (MD , -3.94; 95% CI , -5.57 to -2.31; p<.001), and headache intensity (MD , -1.77 out of 5; 95% CI , -2.42 to -1.11; p<.001) compared with wait-list controls. However, the identified studies had incomplete reporting and uncertain risk of bias, limiting confidence in the estimates.

Section Summary: Migraine and Tension-Type Headache
The evidence on biofeedback for the treatment of migraines and tension-type headaches includes meta-analyses of numerous RCTs. Systematic reviews have found significant effects of biofeedback on headache frequency and intensity in both children and adults. Biofeedback in combination with relaxation is more effective than relaxation alone, suggesting that these act independently.

Cluster Headache

Clinical Context and Therapy Purpose
The purpose of biofeedback for patients who have cluster headache is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals who suffer from cluster headache.

Interventions
The therapy being considered is biofeedback.

Comparators

The following therapy is currently being used to treat cluster headache: standard therapy without biofeedback.

Outcomes
The general outcomes of interest are reductions on instances and intensity of cluster headache and reduction in medication usage. The American Headache Society[2,] identified the following treatment goals of preventive biobehavioral therapy (including biofeedback):

- Reduced frequency and severity of headache;
- Reduced headache-related disability;
- Reduced reliance on poorly tolerated or unwanted pharmacotherapies;
- Enhanced personal control of migraine;
- Reduced headache-related distress and psychological symptoms.

Follow-up over the course of 10 to 20 sessions would be of interest to monitor for outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Only small case series and case reports were identified in the treatment of cluster headache with biofeedback. No controlled trials were found.

Summary of Evidence
For individuals who have migraines or tension-type headaches who receive biofeedback, the evidence includes RCTs and systematic reviews of these trials. The relevant outcomes are symptoms, functional outcomes, and quality of life. The literature, which includes meta-analyses of a large number of controlled and uncontrolled studies, has suggested that this treatment can reduce the frequency and/or severity of migraines and tension-type headaches. Biofeedback, along with other psychologic and behavioral techniques (e.g., relaxation training) may be particularly useful for children, pregnant women, and other adults who are unable to take certain medications. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have cluster headaches who receive biofeedback, the evidence includes small case series and case reports. The relevant outcomes are symptoms, functional outcomes, and QOL. No controlled trials were identified on biofeedback for cluster headache. The evidence is insufficient to determine the effects of the technology on health outcomes.

Chronic Pain

Clinical Context and Therapy Purpose

The purpose of electromyography (EMG) biofeedback in individuals who have chronic pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with chronic pain, including low back, knee, neck and shoulder, orofacial, and abdominal pain as well as fibromyalgia, osteoarthritis, systemic lupus erythematosus, and vulvar vestibulitis.

Interventions
The therapy being considered is EMG biofeedback.

Comparators
The following therapies are currently being used to treat chronic pain: pharmacologic and nonpharmacologic therapy. For chronic pain management, a multimodal, multidisciplinary approach that is individualized to the patient is recommended. [1] A multimodal approach to pain management consists of using treatments (e.g., nonpharmacologic and pharmacologic) from one or more clinical disciplines incorporated into an overall treatment plan. This allows for different avenues to address the pain condition, often enabling a synergistic approach that impacts various aspects of pain, including functionality. The efficacy of such a coordinated, integrated approach has been documented to reduce pain severity, improve mood and overall quality of life, and increase function.

Outcomes
The general outcomes of interest are reductions in symptoms and medication usage and improvements in functional outcomes.

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommends that chronic pain trials should consider assessing outcomes representing 6 core domains: pain, physical functioning, emotional functioning, participant ratings of improvement and satisfaction with treatment, symptoms and adverse events, and participant disposition.[2] Table 1 summarizes provisional benchmarks for interpreting changes in chronic pain clinical trial outcome measures per IMMPACT.[3]

Table 1. Benchmarks for Interpreting Changes in Chronic Pain Outcome Measures

Outcome Domain and Measure	Type of Improvement	Change
Pain intensity 0 to 10 numeric rating scale	Minimally important Moderately important Substantial	10 to 20% decrease ≥30% decrease ≥50% decrease
Physical functioning Multidimensional Pain Inventory Interference Scale Brief Pain Inventory Interference Scale	Clinically important Minimally important	≥0.6 point decrease 1 point decrease

Emotional functioning Beck Depression Inventory Profile of Mood States Total Mood Disturbance Specific Subscales	Clinically important Clinically important Clinically important	≥5 point decrease ≥10 to 15 point decrease ≥2 to 12 point change
Global Rating of Improvement Patient Global Impression of Change	Minimally important Moderately important Substantial	Minimally improved Much improved Very much improved

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

General Chronic Pain

Systematic Reviews
Several meta-analyses have reviewed RCTs assessing psychological therapies for a variety of non-headache chronic pain conditions. A Cochrane review by Williams et al (2020) focused on chronic pain in adults. [4] Two RCTs were identified that compared behavioral therapy with an active control designed to change behavior (e.g., exercise or instruction). Three RCTs had sufficient follow-up to be included in a comparison of behavioral therapy and usual treatment. Reviewers found no evidence that behavioral therapy had any effect on pain compared to active control or usual treatment. Additionally, there was no evidence of a difference between behavioral therapy and active control or usual treatment in terms of disability at the end of treatment.

A Cochrane review by Fisher et al (2018) focused on children and adolescents with chronic and recurrent pain. [5] Although psychological therapies were found to improve pain, only 1 study evaluated biofeedback in nonheadache pain. Biofeedback did not improve abdominal pain more than cognitive-behavioral therapy (CBT) in this trial [6]; see the section on Abdominal Pain). Palermo et al (2010) published a meta-analysis of studies on psychological therapies for the management of chronic pain in children and adolescents.[7] These authors did not identify any additional RCTs on biofeedback for managing nonheadache pain.

Low Back Pain

Systematic Reviews

A Cochrane review by Henschke et al (2010) assessed behavioral treatments for chronic low back pain and conducted a meta-analysis of 3 small randomized trials that compared EMG biofeedback with a waiting-list control group.[8] In the pooled analysis, there were a total of 34 patients in the intervention group and 30 patients in the control group. The standardized mean difference (SMD) 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. Reviewers did not conduct meta-analyses of trials comparing biofeedback with sham biofeedback and therefore were unable to control for any nonspecific effects of treatment.

Randomized Controlled Trials

Yelden et al (2024) compared biofeedback to physiotherapist feedback in an RCT in 40 patients with chronic nonspecific low back pain.[9,] All patients received 12 sessions of the designated therapy (3 sessions weekly for 4 weeks) and a core stabilization activity program. The primary outcome, disability as measured by the Revised Oswestry Disability Index scale was not significantly different between groups at the end of treatment. Secondary measures of visual analogue scale pain scores, muscle activity, and quality of life were also not different between groups.

At least one RCT has compared biofeedback with a sham intervention for the treatment of low back pain. Kapitza et al (2010) compared the efficacy of respiratory biofeedback with sham biofeedback in 42 patients with low back pain.[10] Both groups showed a reduction in pain levels on a 10-point visual analog scale (VAS) at the end of the intervention period and at 3-month follow-up. Between-group differences were not statistically significant. For example, 3 months after the intervention, mean change in pain with activity decreased by 1.12 points in the intervention group and 0.96 points in the sham control group ($p>.05$); mean change in pain at rest decreased by 0.79 points in the intervention group and 0.49points in the control group ($p>.05$).

Lazaridou et al (2023) conducted a prospective, single-center RCT to assess the impact of surface EMG biofeedback versus continued care (no intervention) on chronic lower back pain in adults.[11] Sixty-six patients were randomized 2:1 to receive EMG biofeedback or no additional intervention for 8 weeks and included in analysis. Compared to usual care, patients receiving EMG biofeedback reported lower pain intensity on the Brief Pain Inventory (BPI) questionnaire after 8 weeks (mean difference [MD], 0.9; 95% CI, -1.07 to -0.32; $p\leq.01$). Compared to baseline scores, individuals in the EMG biofeedback group demonstrated statistically significant reductions in pain interference (MD, 1.3; 95% CI, 0.42 to 2.1; $p\leq.01$), disability (MD, 4.32; 95% CI, 1.2 to 7.3; $p\leq.01$), and significant increases in low back pain thresholds (MD, 0.5; 95% CI, -0.87 to -0.05; $p\leq.01$). Significant changes were also observed in muscle tension for the lower back muscles in the EMG biofeedback group ($p<.001$).

Several trials with active comparison groups have not found that biofeedback is superior to alternative treatments. Tan et al (2015) evaluated 3 self-hypnosis interventions and included EMG biofeedback as a control intervention.[12] This RCT enrolled 100 patients with chronic low back pain. After the 8-week intervention, reported reductions in pain intensity were significantly higher in the combined hypnosis groups compared with the biofeedback group ($p=.042$).

A trial published by Glombiewski et al (2010) assessed whether the addition of EMG biofeedback to CBT improved outcomes in 128 patients with low back pain.[13] Patients were randomized to one of three groups: CBT, CBT plus biofeedback, or waiting-list control. Both treatments improved outcomes including pain intensity compared with the 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.

Chronic Knee Pain

Systematic Reviews

Ananias et al (2024) conducted a systematic review and meta-analysis of 8 RCTs that compared the efficacy of biofeedback and standard rehabilitation in patients undergoing anterior cruciate ligament reconstruction surgery.[14] Four of the RCTs were included in the meta-analysis. Two RCTs showed a significant effect of biofeedback on quadriceps strength, 2 studies reported a significant difference in pain scores, 2 studies found a significant difference in knee extension deficit, and one study reported a significant difference in balance. The heterogeneity of outcomes assessed limits the interpretation of these results in this subset of studies.

Karaborklu Argut et al (2022) conducted a systematic review of 8 RCTs of patients who had undergone orthopedic knee surgery.[15] Therapeutic EMG biofeedback during rehabilitation was more effective for improving muscle strength and activation compared to home exercise, standard rehabilitation, or electrical stimulation. There were no clear trends in the effect of EMG biofeedback on pain or knee range of motion.

Collins et al (2012) published a systematic review and meta-analysis of RCTs on nonsurgical interventions for anterior knee pain.[16] In a pooled analysis of data from 2 trials, there was no significant benefit of adding EMG biofeedback to an exercise-only intervention at 8 to 12 weeks (standard mean difference [SMD], -0.22; 95% CI, -0.65 to 0.20).

Chronic Neck and Shoulder Pain

Systematic Reviews

Campo et al (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.[17] The review included 15 RCTs with 8 studies utilizing EMG biofeedback and 7 studies pressure biofeedback (Table 2). 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. An overview of the characteristics and results is presented in Tables 3 and 4. 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 et al (2021) completed a systematic review and meta-analysis of 5 RCTs that examined the effects of EMG biofeedback for shoulder pain and function.[18] Study characteristics and results are presented in Tables 3 and 4. Overall, the evidence did not support the use of EMG biofeedback for reducing shoulder pain and improving shoulder function.

Table 2. Comparison of Studies Included in Systematic Reviews and Meta-Analyses

Study	Campo et al (2021)[15]	Kamonseki et al (2021)[16]
Juul-Kristensen et al (2019)		

Kamonseki et al (2021)	To Dec 2020	5	Adults with shoulder pain	272 (15-72)	RCT (all EMG)	4 weeks to 6 months (follow-up period)

EMG: electromyography; RCT: randomized controlled trial.

Table 4. Systematic Review and Meta-Analysis Results

Study	Pain (short-term: 4 to 6 weeks)	Pain (intermediate-term: 8 to 12 weeks)	Disability (short-term: 4 to 6 weeks)	Disability (intermediate-term: 8 to 12 weeks)	Work ability (short-term: 4 to 6 weeks)	Work ability (intermediate-term: 8 to 12 weeks)
Campo et al (2021)						
Total N	602 (11 RCTs)	383 (6 RCTs)	627 (9 RCTs)	458 (5 RCTs)	190 (3 RCTs)	190 (3 RCTs)
Between-group difference in SMC (95% CI)	-0.26 (-0.77 to 0.24)	-0.15 (-0.34 to 0.05)	-0.42 (-0.59 to -0.26)	-0.30 (-0.53 to -0.06)	-0.01 (-0.26 to 0.28)	-0.03 (-0.26 to 0.31)
Certainty of Evidence[a]	Moderate	Low	Moderate	Moderate	Low	Low
Kamonseki et al (2021)[16,]						
	Shoulder pain intensity	Shoulder function				
Total N	250 (5 RCTs)	175 (3 RCTs)				
SMD (95% CI)	-0.21 (-0.67 to 0.34)	-0.11 (-0.41 to 0.19)				
p value (I^2)	.36 (65%)	.48 (0%)				
Quality of Evidence[a]	Very low	Very low				

CI: confidence interval; RCT: randomized controlled trial; SMC: standardized mean change; SMD: standardized mean difference.

[a] High certainty: we are very confident that the true effect lies close to that of the estimate of the effect; moderate certainty: we are moderately confident in the effect estimate.; low certainty: our confidence in the effect estimate is limited; very low certainty: we have very little confidence in the effect estimate.

Randomized Controlled Trial

de Oliveira et al (2022) conducted an RCT in 24 patients with subacromial pain syndrome who received exercise or exercise plus EMG biofeedback for 8 weeks.[36] The primary outcomes were pain and shoulder function. At 8 weeks, pain was better in the exercise-only group (mean numeric pain rating, 0.5 vs 2 with exercise plus biofeedback; p=.01); however, this outcome was not different between groups at other time points. The only other significant finding was forward rotation of the scapula, which was better in the biofeedback group at 12 weeks (p=.006). All other outcomes were similar between groups.

Ribeiro and Silva (2019) published a RCT assessing whether visual feedback improves range of motion in patients with chronic idiopathic neck pain.[37] Forty-two patients from a single Portuguese clinic were included in the study and randomly assigned to either the visual

feedback group (n=21) or the control group (n=21). There was no effect of time and intervention on pain intensity (p=.729) , but there was a significant interaction between time and intervention in neck flexion (p<.001). The study was limited by its small sample size, short duration of intervention, and by the researcher assessing patients not being blinded.

Orofacial Pain

Systematic Reviews

A Cochrane review by Aggarwal et al (2011) identified 17 trials evaluating nonpharmacologic psychological interventions for adults with chronic orofacial pain (e.g., temporomandibular joint [TMJ] disorder).[38] For studies reporting on short-term pain relief (≤3 months), a significantly greater reduction in pain was found for interventions that combined CBT and biofeedback compared with usual care (2 studies; SMD=0.46; 95% CI, 0.02 to 0.90). However, when the authors reviewed results from studies reporting on long-term pain relief (≥6 months), no significant benefit was found with a combined intervention of CBT/biofeedback and there were no studies that compared CBT alone versus CBT plus biofeedback. For studies reporting on biofeedback-only interventions, a pooled analysis of 2 studies on short-term pain relief did not find a significant benefit compared with usual care (SMD = -0.41; 95% CI, -1.06 to 0.25). There was only one study reporting long-term pain relief after a biofeedback-only intervention, so a pooled analysis could not be done. 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 comprising the review were few in number and had a high-risk of bias.

The conclusions drawn from this Cochrane review are similar to previous systematic reviews on the treatment of temporomandibular joint disorder .[39,40] These older reviews also concluded that there is weak evidence that psychosocial/physical therapy interventions (including biofeedback) are beneficial for treating TMJ disorder and that of the few studies available, they tended to be of poor methodologic quality.

Abdominal Pain

Systematic Reviews

In a systematic review of therapies for recurrent abdominal pain in children by Weydert et al (2003), the behavioral interventions of CBT and biofeedback had a general positive effect on nonspecific recurrent abdominal pain and were deemed safe.[41] The specific effects of biofeedback were not isolated in this systematic review and therefore cannot be assessed.

Randomized Controlled Trials

In a study by Humphreys and Gevirtz (2000), 64 children and teenagers diagnosed with recurrent abdominal pain were randomized to groups treated with increased dietary fiber; fiber and biofeedback; fiber, biofeedback, and CBT; or fiber, biofeedback, CBT, and parental support.[6] The similar nature of the three multicomponent treatment groups was associated with greater pain reduction than the fiber-only group. This trial did not address placebo effects.

Fibromyalgia

Systematic Reviews

Glombiewski et al (2013) published a systemic review and meta-analysis of RCTs reporting data on the efficacy of EMG and electroencephalography (EEG) biofeedback (i.e.,

neurofeedback) for treating patients with fibromyalgia.[42] Reviewers identified seven RCTs that compared EEG biofeedback with a control method in patients with fibromyalgia. Studies in which biofeedback was evaluated only as part of multicomponent interventions were excluded. Three studies used EEG biofeedback and 4 used EMG biofeedback (total n=321 patients). A sham intervention was used as a control condition in four studies, two using EEG biofeedback and two using EMG biofeedback. In a pooled analysis of the studies using EMG biofeedback, a significant reduction in pain intensity was found compared with a different intervention (effect size, Hedges g=0.86; 95% CI, 0.11 to 0.62). A pooled analysis of studies on EEG biofeedback did not find a significant benefit in pain reduction compared with control methods. Pooled analyses of studies of EMG and EEG biofeedback did not find a significant benefit of either intervention on other outcomes such as sleep problems, depression, and health related QOL. None of the studies reviewed were of high quality, with the risk of bias assessed as unclear or high for all included studies. In addition, all studies reported short-term outcomes, resulting in a lack of evidence on whether longer-term outcomes improved with these interventions.

Randomized Controlled Trials

In a small, double-blind RCT from Asia, Babu et al (2007) compared actual and sham biofeedback for effects on pain, fitness, function, and tender points in 30 patients with fibromyalgia.[43] Pain reduction, as assessed on a VAS, did not differ significantly between groups. The trialists calculated that a sample size of 15 patients could detect a difference of 5 cm (on a 10-cm scale) on a VAS, suggesting that the trial lacked adequate power.

A larger unblinded RCT by van Santen et al (2002) evaluated 143 women with fibromyalgia and compared EMG biofeedback with fitness training and with usual care.[44] The primary outcome was pain measured on a VAS. Compared with usual care, the investigators reported no clear improvements in objective or subjective patient outcomes with biofeedback (or fitness training).

Another RCT on EMG biofeedback for fibromyalgia is that by Buckelew et al (1998), which enrolled 119 patients; however, the trial did not follow a double-blind design.[45] Patients were randomized to one of four treatment groups: (1) biofeedback/relaxation training, (2) exercise training, (3) combination treatment, and (4) an educational/attention control program. While the combination treatment group had better tender point index scores than other treatment groups, this trial did not address placebo effects or the impact of adding biofeedback to relaxation therapy.

Osteoarthritis

Systematic Reviews

A systematic review by Macfarlane et al (2012) evaluated practitioner-based complementary and alternative medicine treatments (defined as any treatment not taken orally or applied topically) for osteoarthritis and identified 2 trials on biofeedback.[46] One was an RCT by Yilmaz et al (2010) that assessed whether the addition of EMG biofeedback to strengthening exercises improved outcomes in 40 patients with knee osteoarthritis.[47] After a three-week treatment period, no significant differences between the two treatment methods relative to pain or QOL were found. The other RCT, published in 2007, compared electrical stimulation with biofeedback-assisted exercise in 50 women with knee osteoarthritis.[48] After four weeks of treatment, there were no statistically significant differences between groups in pain and functioning scores.

Systemic Lupus Erythematosus

Randomized Controlled Trials

In an RCT by Greco et al (2004), of 92 patients with systemic lupus erythematosus (SLE), those treated with 6 sessions of biofeedback-assisted CBT for stress reduction had statistically significant greater improvements in pain posttreatment than a symptom-monitoring support group (p=.044) and a group receiving usual care (p=.028).[49] However, these improvements in pain were not sustained at nine-month follow-up.

Vulvar Vestibulitis

Randomized Controlled Trials

A randomized study by Bergeron et al (2001) of 78 patients with dyspareunia resulting from vulvar vestibulitis compared treatment with EM biofeedback, surgery, or CBT.[50] Patients who underwent surgery had significantly better pain scores than patients who received biofeedback or CBT. No placebo treatment was used.

Summary of Evidence: Chronic Pain

For individuals who have chronic pain (including low back, knee, neck and shoulder, orofacial, and abdominal pain as well as fibromyalgia, osteoarthritis, systemic lupus erythematosus, and vulvar vestibulitis) who receive biofeedback, the evidence includes multiple randomized controlled trials (RCTs) for different pain syndromes. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. The results of these RCTs, some of which are sham-controlled, do not consistently report benefit for biofeedback. Some RCTs have reported improved outcomes with biofeedback, but these improvements are often of uncertain clinical significance or are not durable. Many other RCTs have found that biofeedback did not provide a significantly greater benefit in outcomes when it was used either instead of or in addition to other conservative interventions such as exercise. Overall, the available RCTs were limited by small sample sizes and high dropout rates. This evidence base does not permit conclusions about the specific effects of biofeedback beyond the nonspecific effects of sham interventions, nor does it permit conclusions about the contribution of biofeedback beyond that of other conservative treatments for pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Miscellaneous Indications

Biofeedback has been proposed as a treatment for a variety of diseases and disorders including anxiety, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud disease, and insomnia. The type of feedback used in an intervention (e.g., visual, auditory) depends on the nature of the disease or disorder being treated. This evidence review focuses on the use of biofeedback for the treatment of hypertension, anxiety, asthma, movement disorders (e.g., motor function after stroke, injury, or lower-limb surgery), and other applications (e.g., conditions not addressed in other evidence reviews on biofeedback).

Anxiety Disorders

Review of Evidence

Systematic Reviews

Goessl et al (2017) published a meta-analysis on the effect of heart rate variability (HRV) biofeedback (HRVB) training on patients with stress and anxiety.[1] Heart rate variability is a measure of cardiac vagal tone. Low HRV is associated with certain psychological states such as anxiety. The literature search identified 24 studies (N=484 patients), published between 1976 and 2015, for inclusion. Sample sizes ranged from 5 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. Only 13 studies included a comparison group (6 waitlist, 3standard of care, 2 sham, 1 daily thought record, 1 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 that HRV had a larger effect on anxiety than the comparators.

The Canadian Agency for Drugs and Technology in Health (2017) published an update to their rapid response report on biofeedback for treating mood and anxiety disorders.[2] This systematic review of the literature did not identify any health technology assessments, systematic reviews, meta-analyses, RCTs, or nonrandomized studies evaluating biofeedback for the treatment of generalized anxiety disorder.

Randomized Controlled Trials

Ma et al (2023) conducted an RCT of the effect of integrated cognitive-behavioral therapy and biofeedback in patients with panic disorder.[38] Patients were randomized to the intervention group (n=15) or treatment as usual (n=15). Pharmacotherapy had to remain stable during the 6-week study. The primary endpoint was the improvement in Panic Disorder Severity Scale (PDSS) at 6 weeks. At baseline, PDSS scores were moderate severity. At 6 weeks, PDSS scores were not significantly different from baseline. The authors did not describe their sample size calculation so the possibility of type 2 error cannot be excluded.

Chen et al (2017) published an RCT comparing diaphragmatic breathing relaxation with routine respiration activities in the treatment of 46 patients with anxiety.[3] Diaphragmatic breathing relaxation 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 the Beck Anxiety Inventory, and 4 physiological measures (skin conductivity, peripheral blood flow, heart rate, breathing rate). All patients participated in an individualized 8-week course in breathing relaxation, but only 30 completed it. Fifteen were randomized to diaphragmatic breathing relaxation 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 8 weeks, the diaphragmatic breathing relaxation group experienced statistically significant decreases in Beck Anxiety Inventory scores compared with baseline, while the control group did not. The diaphragmatic breathing relaxation group also experienced significant improvements in all 4 physiological measurements, while the control group did not.

Section Summary: Anxiety Disorders

For individuals with anxiety disorders who receive biofeedback, the evidence includes 2 systematic reviews and RCTs published after the review. A systematic review on HRVB and an RCT on diaphragmatic breathing relaxation reported the positive effects of these treatments on anxiety. However, the trials in the systematic review had small sample sizes (median, 14 participants) and study quality was generally poor. Additional limitations included improper randomization, allocation concealment, and inadequate descriptions of randomization or missing data. The other RCT did not find a significant effect of biofeedback, possibly due to lack of power.

Asthma

Review of Evidence

Systematic Reviews

Yorke et al (2015) published a systematic review evaluating nonpharmacologic interventions for the treatment of adults with asthma.[4] 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 3 biofeedback RCTs used different techniques: exhaled carbon dioxide capnography (pooled n=12)[5]; HRV using a physiograph (pooled n=94 patients)[6]; and respiratory sinus arrhythmia by electrocardiographic feedback and muscle tension by electromyography (EMG; pooled n=17 patients).[7] Common outcomes in the 3 trials 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 1 second were found and medication use decreased in only one trial. Reviewers concluded that larger sample sizes were needed to demonstrate effects and differences between treatment groups did not translate into meaningful clinical benefits.

Randomized Controlled Trials

Taghizadeh et al (2019) hypothesized that HRVB could decrease vulnerability to stress-induced pulmonary impairment in patients with asthma.[8] Twenty-two healthy women and 22 women with asthma participated in the study. Eleven participants from each group were randomly allocated to either HRVB or a control group. Using spirometry, all participants' lung function was tested at baseline and after performing the Stroop color-word task. Before the 10-minute Stroop test, each group underwent 20 minutes of either HRVB (treatment group) or maintained a state of relaxed alertness while listening to classical music (control group), after which the groups had similar stress levels as self-reported on a visual analog scale. After the test, all participants again rated their stress levels. All 4 groups were statistically significantly stressed ($p<.001$). Although the healthy group who underwent HRVB reported significantly less

stress than the healthy control group (p=.034), the participants with asthma did not experience this effect. In fact, larger stress-induced HRV changes suggested an exaggerated response in asthmatic participants compared to the healthy ones. However, spirometry parameters, which were monitored throughout the experimental procedures, showed that HRVB had a protective effect on the participants with asthma as well as enhanced the level of forced expiratory volume percent (p=.002) and forced vital capacity percent (p<.001) compared to baseline. The authors concluded that HRVB is a promising protective approach to aid lung function and reduce asthma exacerbation caused by stress. Some limitations of the study include using only the Stroop test to induce stress, measuring stress on a subjective visual analog scale, and including only female participants.

Lehrer et al (2018) examined the efficacy and safety of HRVB on asthma to determine if the treatment could substitute for the controller or rescue medication and whether HRVB controls airway inflammation.[9] In the 2-center trial, 68 paid steroid-naive volunteers with mild-to-moderate asthma received 3 months of HRVB or a comparison condition consisting of electroencephalography alpha biofeedback with relaxing music and relaxed paced breathing. Both treatment conditions showed similar significant improvements on the methacholine challenge test, asthma symptoms, and asthma QOL, and the administration of albuterol after biofeedback sessions produced a large improvement in pulmonary function test results. Trial data suggest that HRVB should not be considered as an alternative to asthma controller medications.

Section Summary: Asthma
For individuals with asthma who receive biofeedback, the evidence includes a systematic review of 3 RCTs and 2 RCTs published after the review. Each RCT used a different biofeedback technique, which provided individuals with information on carbon dioxide, heart rate, and respiratory sinus arrhythmia. While the trials reported improvements in each parameter for which the patients received biofeedback, the improvements did not impact clinical outcomes such as medication use and forced expiratory volume. However, the results of 1 RCT suggested that biofeedback has promise as a protective approach in aiding lung function and reducing stress-induced asthma exacerbation.

Bell Palsy

Review of Evidence

Systematic Reviews
Cardoso et al (2008) published a systematic review on the effects of facial exercises on symptoms of Bell palsy.[10] Studies including patients with unilateral idiopathic facial palsy treated with facial exercises associated with mirror and/or EMG biofeedback were selected. Four studies (N=132 patients) met the eligibility criteria. The studies described mime therapy versus control (n=50 patients), mirror biofeedback exercise versus control (n=27 patients), “small” mirror movements versus conventional neuromuscular retraining (n=10 patients), and EMG biofeedback plus mirror training versus mirror training alone. The treatment length varied from 1 to 12 months. Reviewers concluded that, given the paucity of RCTs, the current evidence does not support the use of biofeedback to treat this population.

Section Summary: Bell Palsy
For individuals with Bell palsy who receive biofeedback, the evidence includes a systematic review of 4 RCTs. The RCTs evaluated the efficacy of adding a mirror and/or EMG

biofeedback to facial exercises. The sample sizes were small, and there was heterogeneity across techniques used and length of treatments.

Depression

Review of Evidence

Systematic Reviews

The Canadian Agency for Drugs and Technology in Health (2014) report on biofeedback for mood and anxiety disorders [11] included a systematic review of the literature on biofeedback for depression. Other than 2 dissertations using HRVB, no health technology assessments, systematic reviews, meta-analyses, RCTs, or nonrandomized studies evaluating biofeedback for the treatment of depression were identified. An update was published in 2017 (previously discussed in the Anxiety section).[2] An additional dissertation using HRVB was included, but no other relevant studies for the treatment of depression were identified.

Randomized Controlled Trials

Since the publication of this systematic review, 2 small RCTs have been published; the characteristics, results, and limitations of these trials are summarized in Tables 1 through 4. Maynart et al (2021) compared respiratory and heart rate biofeedback plus usual care to usual care alone in 36 patients with moderate to severe depression or dysthymia.[12] After 6 weeks (6 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. An additional preliminary open-label RCT by Park and Jung (2020) compared respiratory sinus arrhythmia biofeedback plus usual care to usual care alone in 30 Korean patients with major depressive disorder.[13] After 4 weeks (6 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.

Table 1. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active Treatment	Comparator
Maynart et al (2021)[12]	Brazil	3	NR	Adults aged 18 years or older with major depressive disorder or dysthymia treated with antidepressants and BDI score of 20 to 63	Respiratory rate and blood volume pulse/heart rate biofeedback plus usual care (n=18)	Usual care alone (n=18)
Park and Jung (2020)[13]	South Korea	1	2015-2018	Adults aged 20 to 60 years with major depressive disorder and HAM-D score of 16 or greater	Respiratory sinus arrhythmia biofeedback (6 sessions) plus usual care (n=16)	Usual care alone (n=14)

BDI: Beck Depression Inventory; HAM-D: Hamilton Depression Rating Scale; NR: not reported.

Table 2. Summary of Key RCT Results

Study	HAM-D	BDI

Maynart et al (2021)[12,]		*% in each BDI severity category at 6 weeks*
Biofeedback plus usual care	NR	Minimum: 16.7% Light: 19.4% Moderate: 13.9% Severe: 0%
Usual care alone	NR	Minimum: 2.8% Light: 13.9% Moderate: 30.6% Severe: 2.8%
p value	NR	.046
Park and Jung (2020)[13,]	*Mean HAM-D score at week 4*	*Mean BDI score at week 4*
Biofeedback plus usual care	8.92	24.33
Usual care alone	14.55	25.45
p value	.0229	.7657

BDI: Beck Depression Inventory; HAM-D: Hamilton Depression Rating Scale; NR: not reported.

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Maynart et al (2021)[12,]			3. No sham biofeedback intervention was administered to the control group		1. Primary outcomes were assessed at the end of 6 weeks; no information available on long- term impact of biofeedback
Park and Jung (2020)[13,]			3. No sham biofeedback intervention was administered to the control group		1. Primary outcomes were assessed at the end of 4 weeks; no information available on long- term impact of biofeedback

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Maynart et al (2021)[12,]		1,2. Open label design			1. Power calculations not detailed	
Park and Jung (2020)[13,]		1,2. Open label design				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Depression

For individuals with depression who receive biofeedback, the evidence includes a systematic review and 2 small RCTs published after the systematic review. The review and its update only identified 3 dissertations assessing the use of biofeedback for depression. One RCT found that respiratory and heart rate biofeedback plus usual care reduced BDI scores compared to usual care alone, while the other found that respiratory sinus arrhythmia biofeedback plus usual care was associated with greater improvements in HAM-D scores compared to usual care alone; however, these trials were limited by open-label designs, short follow-up periods, and small sample sizes.

Hypertension

Review of Evidence

Systematic Reviews

Jenkins et al (2024) published a systematic review and meta-analysis of biofeedback in patients with hypertension.[39] Twenty studies (N=988 patients) met the inclusion criteria, which represented 6 methods of providing biofeedback. The number of sessions ranged from 4 to 48 and follow-up ranged from 2 weeks to 12 months. There was a significant effect on both systolic (mean, -4.52 mm Hg) and diastolic blood pressure (mean, -5.19 mm Hg) with biofeedback (p=.02 and p=.0004, respectively). Limitations of this analysis include heterogeneity in the included studies.

A systematic review of studies on biofeedback for hypertension was published by Greenhalgh et al (2009).[14] Reviewers searched for RCTs that included adults with essential hypertension (defined as at least 140/90 mm Hg) and that compared biofeedback interventions, alone or in combination, with other therapies, to medication, sham biofeedback, no treatment, or another behavioral intervention. Thirty-six trials (N=1660 patients) met inclusion criteria. Trials generally were small; only 4 included more than 100 patients. All were single-center, and most

were conducted in the U.S. Trials used a variety of biofeedback techniques including thermal biofeedback, galvanized skin response, pulse wave velocity, and HRV; some used more than 1 modality. Twenty studies evaluated biofeedback alone, 15 evaluated biofeedback combined with another intervention, and 1 had multiple arms and evaluated both types of interventions; only 4 trials included a sham biofeedback comparison group. Reviewers stated that they did not pool study findings due to differences in interventions and outcomes and the generally poor quality of the studies.

Reviewers reported that trials comparing biofeedback alone with no treatment or another behavioral intervention did not provide convincing evidence of the superiority of biofeedback. Only 1 of 5 trials that compared a biofeedback combination intervention (most commonly combined with relaxation) with a different behavioral treatment found the biofeedback intervention to be superior. Approximately half of the trials comparing a biofeedback combination with no treatment found a significant benefit to the biofeedback combination, but the specific effects of biofeedback could not be determined from this analysis. Only 1 trial compared a biofeedback combination intervention with sham biofeedback, and it did not find a significant difference in the efficacy of the 2 interventions. Four studies on biofeedback alone and another 4 on a combined biofeedback intervention reported data beyond 6 months; most of them found no significant differences in efficacy between the biofeedback and control groups.

Randomized Controlled Trials

Wang et al (2016) published an RCT evaluating the effect of direct blood pressure biofeedback in patients with prehypertension or stage I hypertension.[15] A trained nurse instructed patients in blood pressure self-regulation by using slow diaphragmatic breathing and passive attitude. During the 8-week training (1 session per week), patients in the treatment group received real-time blood pressure feedback signals (n=29) and the control group received pseudo- feedback signals (n=28). Outcomes were systolic and diastolic blood pressure, measured at baseline and 1 and 8 weeks after training. Both groups significantly decreased blood pressure following training. The decreases were equal in magnitude, suggesting that blood pressure self-regulation training could effectively lower blood pressure, regardless of the type of feedback signal.

Mengden et al (2023) published a randomized cohort study evaluating the effect of device-guided slow breathing with biofeedback of pulse wave velocity in patients with hypertension.[16] Patients (N=44) were trained to perform unattended device-guided slow breathing exercises for 10 minutes daily over 5 days. At the time of initial screening, median office-measured blood pressure was 137/83 mmHg. After the first 10 minute daily exercise, a significant increase ($p<.05$) in pulse wave velocity of 5 ms on average was observed. Additionally, between the initial baseline collection of blood pressure and self-assessment before beginning the breathing assessment, there was a significant decrease of 6 mmHg ($p<.001$) in systolic blood pressure, possibly accounting for white coat effect. Another significant 5 mmHg ($p<.001$) decrease in systolic blood pressure occurred post-assessment. Similar changes were seen daily after each biofeedback session. However, there were no significant changes between day 1 values and day 5 values.

Section Summary: Hypertension

For individuals with hypertension who receive biofeedback, the evidence includes 2 systematic reviews and 2 RCTs published after the review. One systematic review identified 36 RCTs, though sample sizes were small and overall study quality poor. Various biofeedback

techniques were used: thermal, galvanized skin response, pulse wave velocity, and HRV. Results across trials did not consistently show a benefit of biofeedback. Conclusions were limited due to the shortage of studies isolating the effect of biofeedback, the generally poor quality of trials, and heterogeneity across interventions used. The other systematic review was smaller (20 RCTs) but found a significant effect of biofeedback on both systolic and diastolic blood pressure. The Mengden 2023 RCT demonstrated an acute change in blood pressure after a 10-min biofeedback session, but no longer term effects were demonstrated over the course of a week.

Motor Dysfunction After Stroke

Review of Evidence

Systematic Reviews

Stanton et al (2017) updated a systematic review and meta-analysis published in 2011, which evaluated the effect of biofeedback on lower-limb activities in patients who have had a stroke.[17,18] Only high-quality RCTs or quasi-RCTs with Physiotherapy Evidence Database scores greater than 4 were included. Training activities were walking (9 trials), standing (8 trials), and standing up (1 trial). Biofeedback techniques included weight distribution from a force platform or sensor (11 trials), muscle activity from EMG (3 trials), linear gait parameters (3 trials), and joint angle from a goniometer (1 trial). Visual feedback was used in 7 trials, auditory in 7 trials, and a combination of visual and auditory in 4 trials. The 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 4 trials provided that information.

A systematic review by Zijlstra et al (2010) focused on studies evaluating biofeedback-based training to improve mobility and balance in adults older than 60 years of age.[19] Although the review was not limited to studies on motor function after stroke, more than half included older adults poststroke. For review inclusion, studies had to include a control group of patients who did not receive biofeedback and to assess at least 1 objective outcome measure. Twelve (57%) of the 21 studies included individuals poststroke, 3 included older adults who had lower-limb surgery, and 6 included frail older adults without a specific medical condition. Individual studies were small, ranging from 5 to 30 patients. The added benefit of using biofeedback could be evaluated in 13 (62%) of 21 studies. Nine of the 13 studies found a significantly greater benefit with interventions that used biofeedback than with control interventions. However, the outcomes assessed were generally not clinical outcomes but laboratory-based measures related to executing a task (eg, moving from sitting to standing) in a laboratory setting and platform-based measures of postural sway. Only 3 studies reported long-term outcomes, and none of them reported a significant effect of biofeedback.

Table 5 summarizes the characteristics of selected systematic reviews.

Table 5. Characteristics of the Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Stanton et al (2017)[17,]	To 2015	18	Lower-limb motor function loss poststroke	429 (12-50)	RCTs	NR
Zijlstra et al (2010)[19,]	1993-2012	21	Patients >60 years receiving biofeedback to improve motor function	NR (5-30)	17 RCTs, 4 other	NR

NR: not reported; RCT: randomized controlled trial

Randomized Controlled Trials

Several RCTs have been published since the systematic reviews discussed above; these studies are described here. The RCTs that reported outcomes in at least 40 patients are highlighted in Tables 6 through 9.

Ambrosini et al (2020) published an RCT on the effect of visual biofeedback on gait and walking ability in patients who had a first-time stroke.[20] Patients were randomized to receive 20 minutes of visual biofeedback training and 70 minutes of usual rehabilitation care (n=34) or 90 minutes of usual rehabilitation care (n=34). Characteristics, results, and limitations of this trial are summarized in the tables below. Groups experienced similar improvements in gait speed, 6- minute walking test, Functional Independence Measure scores, and Berg Balance Test scores, with no significant differences between groups observed. Outcomes were reported at the end of 6 weeks of treatment; although follow-up was attempted at 6 months, over half of the patients were unavailable for follow-up assessments, so longer term effects of biofeedback training could not be assessed.

Ghanbari Ghoshchi et al (2020) published an RCT on the effects of technological rehabilitation (using audio or visual biofeedback) on activities of daily living and return to work among 48 patients who had a stroke. [21] All patients attended 3 rehabilitation sessions per day on 3 days per week for 1 month; each session was 40 minutes in length. Patients randomized to the technological rehabilitation group had 400 minutes of audio or visual biofeedback training included in their rehabilitation sessions. Ability to perform activities of daily living was measured using the modified Barthel Index. Trial characteristics, results, and limitations are summarized in the tables below. No significant between- group differences were observed 6 months after therapy was completed. Return to work may have been influenced by other factors, including patient age, economic status, and previous occupation.

Kim (2017) published an RCT on the effect of EMG on upper-extremity function in patients who had a stroke.[22] Patients were randomized to traditional rehabilitation therapy (n=15) or traditional rehabilitation therapy plus EMG biofeedback training (n=15). The upper-limb function was measured by the Fugl-Meyer Assessment and the Manual Function Test, and activities of daily living were measured using the Functional Independence Measure instrument. Both Fugl-Meyer Assessment and the Manual Function Test scores improved significantly more in patients receiving EMG biofeedback. However, there was no significant difference in Functional Independence Measure score improvement between groups.

Yang (2016) published an 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.[23] 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 the center of pressure). Comparison statistics were calculated for pre- and post-training results, and between treatment groups. The biofeedback group significantly improved on both outcomes compared with the control group.

Ghomashchi (2016) published an RCT that evaluated the effect of visual biofeedback on postural balance disorders in patients who had a stroke.[24] 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.

Table 6. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active Treatment	Comparator
Ambrosini et al (2020)[20]	Italy	1	2015-2018	Adults aged 18 to 90 years in an inpatient rehabilitation facility with first stroke <6 months prior to recruitment and hemiparesis; had to have lower limb range of motion that allowed pedaling and reduced spasticity of leg muscles (Modified Ashworth scale <2)	20 minutes of visual biofeedback training (voluntary cycling augmented by functional electrical stimulation or platform-based balance training) plus 70 minutes of usual care per session; 30 sessions (n=34)	90 minutes of usual care per session; 30 sessions (n=34)
Ghanbari Ghoshchi et al (2020)[21]	Italy	3	NR	Adults aged 18 to 66 years in neurorehabilitation hospitals with stroke >6 months prior to the study who were working at the time of their stroke	Technological rehabilitation; patients received 400 minutes total of audio or visual biofeedback via SonicHand or Riablo devices as part of their rehab sessions, in addition to conventional exercises (n=23)	Conventional rehabilitation; patients performed conventional rehabilitation exercises only for the same total amount of time (n=25)

NR: not reported.

Table 7. Summary of Key Randomized Controlled Trial Results

Study	Gait speed	6-minute walking test	Functional Independence Measure	Berg Balance Test	Modified Barthel Index	Return to work	Fall events
Ambrosini et al (2020)[20]	*Change from baseline to posttreatment*	*Change from baseline to posttreatment*	*Change from baseline to posttreatment in the motor subscale*	*Change from baseline to posttreatment*			
Biofeedback	27.7 cm/s	110.2 m	35	21	NR	NR	NR
Usual care	21.3 cm/s	76.1 m	31	18	NR	NR	NR
p value	.305	.120	.451	.211	NR	NR	NR
Ghanbari Ghoshchi et al (2020)[21]						*At 6-month follow-up*	*At 6-month follow-up*
Technological rehabilitation with biofeedback	NR	NR	NR	NR	Postrehab: 88 6-month follow-up: 100	11 (47.8%)	5 (21.7%)
Conventional rehabilitation	NR	NR	NR	NR	Postrehab: 80 6-month follow-up: 95	9 (36.0%)	4 (16.0%)
p value	NR	NR	NR	NR	Postrehab:.391 6-month follow-up:.450	.406	.611

NR: not reported.

Table 8. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Ambrosini et al (2020)[20]					1. Primary outcomes were assessed at the end of 6 weeks of treatment; 6-month follow-up was attempted, but 53% of patients were not available for assessment
Ghanbari Ghoshchi et al (2020)[21]					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 9. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Ambrosini et al (2020)[20]		1. Single-blind design (patients not blinded)		1. High drop-out rate (24% at posttreatment time point, 53% at 6-month follow-up)		
Ghanbari Ghoshchi et al (2020)[21]		1. Single-blind design (patients not blinded)			1. Power calculations not reported	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Motor Dysfunction After Stroke

For individuals with motor dysfunction after stroke who receive biofeedback, the evidence includes systematic reviews and RCTs published after the systematic reviews. One systematic review identified 18 high-quality trials using the following biofeedback techniques: weight distribution on a platform sensor, muscle activity from EMG, linear gait parameters, and joint angle from a goniometer. Feedback was visual, auditory, or both. Outcome measures primarily assessed motor activity in research settings, rather than clinical outcomes such as rates of falls or the ability to perform activities of daily living. Pooled effects showed improvements in motor function in the short term. The evidence is limited due to the variability in type, duration, and intensity of the interventions and lack of long-term outcomes. The largest available studies published since the systematic reviews found no differences between biofeedback-assisted rehabilitation and conventional rehabilitation in impact on gait speed, balance, activities of daily living, fall rate, and return to work.

Motor Dysfunction After Lower-Limb Injury or Surgery

Review of Evidence

Systematic Reviews

A systematic review by Silkman and McKeon (2010) evaluated the effectiveness of EMG biofeedback for improving muscle function during knee rehabilitation after injury.[25] 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, while the others did not. The positive studies assessed intermediate outcomes (e.g., contraction values of the quadriceps muscles). None of the studies were designed to assess functional outcomes.

A systematic review and meta-analysis by Xie et al (2021) included 6 RCTs (N=222) comparing postsurgical knee rehabilitation programs with and without EMG biofeedback.[26] Sample sizes of individual trials ranged from 16 to 66 patients. In a meta-analysis of data from 5 RCTs (n=146), range of motion was improved with biofeedback (standardized mean difference, -0.48; 95% CI, -0.82 to -0.14; p=.006; I^2=37%). However, 4 of the 5 individual trials in the range of motion analysis found no significant benefit with EMG biofeedback compared to conventional rehabilitation methods; only the smallest trial (N=16), measuring passive range of motion 6 weeks after anterior cruciate ligament reconstruction, found a significant improvement with EMG biofeedback. The studies were heterogenous in terms of the intervention intensity, the comparators used, and the type of knee surgery, as well as the specific range of motion endpoint used (passive vs. active range of motion). The range of motion findings of the meta-analysis may have been driven by the strong positive findings in a single trial, and may not be generalizable to other settings. Biofeedback was not associated with greater improvements in pain or physical function. Trials were generally limited by small sample sizes and short follow-up periods.

Section Summary: Motor Dysfunction After Lower-Limb Injury or Surgery

For individuals with motor dysfunction after lower-limb injury or surgery who receive biofeedback, the evidence includes 2 systematic reviews. One systematic review identified 4 RCTs evaluating the use of EMG biofeedback in patients undergoing postinjury knee rehabilitation. Sample sizes were small, with half of the trials reporting significant benefits of biofeedback and the other half reporting no difference between study groups. The other systematic review identified 6 RCTs evaluating the use of EMG biofeedback in patients undergoing postsurgical knee rehabilitation. Biofeedback was associated with better range of motion outcomes in a meta-analysis of data from 5 RCTs, but was not associated with a significant benefit in pain or physical functioning. Larger and longer-term trials are still needed that demonstrate benefits on quality of life and functional outcomes.

Multiple Sclerosis

Review of Evidence

Randomized Controlled Trials

An RCT by MacKay et al (2015) evaluated the addition of biofeedback to standard care in 40 patients with relapsing-remitting multiple sclerosis patients.[27] The standard of care psychosocial intervention consisted of relaxation, mindfulness, social support, and education.

All patients attended 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 the use of biofeedback equipment for self-regulation. Following the three weekly sessions, patients were instructed to practice the exercises at home, with or without the use of biofeedback equipment. Outcomes included breathing rate and anxiety, depression, fatigue, and muscle tension measures. At the end of treatment, there were no statistically significant differences between groups in any outcomes. For example, the differences between the intervention group and the control group in breathing rate were 3.06 breaths per minute (95% CI, -0.17 to 6.28 breaths per minute; p=.06) and the difference in muscle tension was -13.91 μV (95% CI, -30.06 to 2.25 μV; p=.09). Both groups received similar amounts of provider contact, so nonspecific intervention effects were not an issue.

A crossover study by van der Logt et al (2016) evaluated the effect of vibrotactile biofeedback of trunk sway on balance control in patients with multiple sclerosis.[28] 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 were significantly different compared with trunk sway when performing the tasks without vibrotactile biofeedback.

Section Summary: Multiple Sclerosis
For individuals with MS who receive biofeedback, the evidence includes 2 RCTs. One trial used vibrotactile biofeedback and the other provided patients with breathing rate and muscle tension biofeedback. The sample sizes were small, with no statistically significant differences between the biofeedback groups and control groups.

Orthostatic Hypotension in Patients with Spinal Cord Injury

Review of Evidence

Systematic Reviews
Gillis et al (2008) conducted a systematic review to identify and describe the body of literature pertaining to nonpharmacologic management of orthostatic hypotension during the early rehabilitation of persons with spinal cord injury.[29] 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. Thirteen studies (total n=138 patients) were included in the review. Four distinct nonpharmacologic interventions for orthostatic hypotension were identified, and only two studies evaluated biofeedback. The 2 studies with 3 patients using biofeedback techniques reported an average of 39% increase in systolic blood pressure. The authors concluded that "…The clinical usefulness of compression/pressure, upper body exercise and biofeedback for treating orthostatic hypotension has not been proven."

Section Summary: Orthostatic Hypotension in Patients with Spinal Cord Injury
For individuals with orthostatic hypotension due to spinal cord injury who receive biofeedback, the evidence includes a systematic review, which included a case series and a case report. The case series and case report collectively provided information on 3 patients given visual

and auditory feedback. Patients were able to raise their systolic blood pressure by an average of 39%.

Pain Management During Labor

Review of Evidence

Systematic Reviews

In a Cochrane review, Barragan Loayza et al (2011) evaluated RCTs on biofeedback for managing pain during labor.[30] Reviewers identified 4 RCTs published between 1982 and 2000 (N=186 women). The studies were highly variable in terms of intervention modalities and outcomes measured, and thus findings were not pooled. In addition, the Cochrane review authors judged the trials to be at high risk of bias (e.g., unclear description of blinding and randomization methods). Overall, the authors found little difference in reported outcomes (e.g., rates of Cesarean section, pharmacologic pain relief in women receiving biofeedback compared with control interventions). Due to the small number of studies and small overall sample size, the evidence is insufficient to draw conclusions about the effectiveness of biofeedback in labor pain control.

Section Summary: Pain Management during Labor

For individuals who need pain management during labor who receive biofeedback, the evidence includes a systematic review of 4 RCTs. A Cochrane review graded the 4 trials as having a high risk of bias due to unclear descriptions of blinding and randomization methods. Due to the heterogeneity in biofeedback methods and outcomes measured, pooled analyses could not be performed.

Posttraumatic Stress Disorder

Review of Evidence

Systematic Reviews

The 2014 Canadian Agency for Drugs and Technology in Health report on biofeedback for mood and anxiety disorders, previously discussed, included a systematic review of the literature on biofeedback for posttraumatic stress disorder (PTSD).[11] One systematic review was identified; this study was published by Wahbeh et al (2014) and addressed a variety of complementary and alternative medicine approaches to treating PTSD.[31] Four of 33 studies that met selection criteria of the Wahbeh et al (2014) review addressed biofeedback. Among the biofeedback studies were one RCT, one nonrandomized trial, and two case series. The controlled trials either had mixed results or did not find a significant benefit of biofeedback. Reviewers gave the biofeedback evidence a grade C for unclear or conflicting scientific evidence. An update of the Canadian Agency for Drugs and Technology in Health report was published in 2017 (previously mentioned).[2] Investigators identified 2 RCTs using biofeedback in patients with PTSD: 1 by Wahbeh et al (2016) compared 4 treatment modalities, including mindfulness meditation, slow breathing using a biofeedback device, mindful awareness of breadth with the intent to do slow breathing, and sitting quietly in combat veterans with PTSD

(N=102); the other RCT by Polak et al (2015) compared biofeedback plus trauma-focused cognitive behavioral therapy (CBT) to CBT alone in patients with PTSD (N=8). The smaller study by Polak et al demonstrated that PTSD symptoms decreased over time for both biofeedback plus CBT and CBT alone, but PTSD symptoms decreased faster with biofeedback plus CBT compared to CBT alone (p=.051). The larger RCT by Wahbeh et al showed that there were no between group differences for biofeedback and various other mindfulness related treatment modalities in individuals with PTSD. These results were limited by the small sample size in Polak et al, lack of adverse event reporting, and the small number of studies which did not allow for pooling of results.

Kenemore et al (2024) conducted a systematic review and meta-analysis of HRVB in military veterans with PTSD.[40] Five studies were included (N=95 patients), all of which reported improvements in PTSD symptoms. All trials were uncontrolled. Effect sizes ranged from -1.614 to -0.414. The mean effect size for biofeedback on PTSD symptoms was -0.557 (95% CI, -0.818 to -0.296; p<.001), indicating a moderate effect.

Section Summary: Posttraumatic Stress Disorder
For individuals with PTSD who receive biofeedback, the evidence includes a systematic review and its update and a second systematic review. The 2014 systematic review included an RCT, a nonrandomized study, and 2 case series. The studies had small sample sizes and inconsistent results. The reviewers rated the evidence a grade C for conflicting scientific evidence. The 2017 systematic review update included 2 new RCTs, one of which demonstrated a faster decrease of PTSD symptoms with biofeedback and CBT compared to CBT alone. However, the small sample size was a limitation. The other RCT found no differences between biofeedback and other treatment modalities.

Prevention of Preterm Birth

Review of Evidence

Randomized Controlled Trials
Siepmann et al (2014) published data on 48 women who had experienced threatened preterm labor between the 24th and 32nd gestational week.[32] Twenty-four patients received 6 biofeedback sessions over 2 weeks, and the other 24 patients were in a usual care group. Preterm delivery occurred in 3 patients (13%) in the biofeedback group and 8 patients (33%) in the control group; the difference between groups was not statistically significant (p>.05). Other gestational outcome data, such as the gestational duration and birthweight, also did not differ significantly between groups.

Section Summary: Prevention of Preterm Birth
For individuals who are susceptible to preterm birth who receive biofeedback, the evidence includes an RCT. In the RCT, women in the treatment group received heart rate variability biofeedback. Patients receiving the treatment experienced a decrease in perceived chronic stress, but there was no significant difference in the number of preterm births, gestational duration, or birth weight.

Raynaud Disease

Review of Evidence

Systematic Reviews

A systematic review by Malenfant et al (2009) assessed the use of complementary and alternative medicine to treat Raynaud disease.[33] Reviewers identified five trials using biofeedback techniques, and they reported a variety of outcomes. A pooled analysis of findings from 4 trials (total N=110) on the change in frequency of attacks favored the sham control group over the biofeedback group (weighted mean difference, -1.21; 95% CI, -1.68 to -0.73; p<.000). Several trials had more than two arms; in the preceding analysis, only the arms comparing active and sham biofeedback were included.

Randomized Controlled Trials

The trial given the highest quality rating by the authors of the systematic review and with the largest sample size was the Raynaud's Treatment Study, published in 2000.[34] This randomized trial compared sustained-release nifedipine with thermal biofeedback in 313 patients with primary Raynaud disease. 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 physiologic mechanism of Raynaud disease. The mean attack rate at 1 year, the primary study outcome, was 0.16 in the thermal biofeedback group, 0.23 in the EMG biofeedback group, 0.07 in the nifedipine group, and 0.21 in the placebo group. Nifedipine significantly reduced Raynaud attacks compared with placebo (p<.002), but thermal feedback did not differ significantly from EMG biofeedback (p=.37). There was not a significant difference in attack rates in the nifedipine and thermal biofeedback [groups for the primary outcome (p=.08).

Section Summary: Raynaud Disease

For individuals with Raynaud disease who receive biofeedback, the evidence includes a systematic review. The systematic review identified 5 RCTs using biofeedback techniques. Pooled analysis was performed on 4 of these trials. The reduction in the frequency of attacks was significantly lower in the sham control group.

Sleep Bruxism

Review of Evidence

Systematic Reviews

Wang et al (2014) published a systematic review of randomized and non-RCTs on biofeedback treatment for sleep bruxism.[35] Seventeen articles were reviewed and seven studies with (N=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 electric stimulation, and one used visual biofeedback. Treatment durations ranged from one night to six weeks. In four studies, treatment duration was two weeks. Three studies at moderate risk of bias, and the other four were considered 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 (n=27 patients) 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.

Jokubauskas et al (2018) updated the systematic review by Wang et al (2014) (above) on the management of sleep bruxism with biofeedback.[36] Five databases were searched for literature published after the original 2012 search. Six relevant publications were included (N=86 adults),

and of these studies, four were RCTs and two were uncontrolled before-after studies. For the quantitative synthesis, 3 studies were used, 2 or which were included from the original Wang et al (2014) review. Contingent electrical stimulation, audio feedback, and a maxillary biofeedback splint were among the biofeedback techniques investigated, and all studies measured sleep bruxism with EMG with the exception of one, which used a mini wireless biofeedback device that analyzed bite force. The primary outcome of the analysis was the number of sleep bruxism episodes per hour detected by EMG recording. Secondary outcomes of sleep quality and pain-related outcomes were also investigated, and one study reported on patient-perceived symptom change. Overall, the quality of these studies was assessed as low to moderate due to imprecision and inconsistency between studies, and the risk of bias was graded as high to moderate. Despite the limitations of the studies, the use of biofeedback to treat sleep bruxism has shown some effectiveness and is relatively safe and noninvasive.

Randomized Controlled Trials

One RCT by Bergmann et al (2020) has been published since the systematic reviews discussed above.[37] This trial(N=41) examined the use of a full-occlusion biofeedback splint for sleep bruxism and pain associated with temporomandibular disorder. The biofeedback splint was compared to an adjusted occlusal splint. The key characteristics and results of the trial are summarized in Tables 10 and 11. Limitations in study relevance, conduct, and design are summarized in Tables 12 and 13. Although a statistically significant difference in total duration of bruxism events per hour was observed at 1 month, this difference was no longer significant at 3 months, and no significant difference was seen in the number of bursts per hour. Patients in the biofeedback splint group had a greater decrease in general pain perception at 3 months.

Table 10. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active Treatment	Comparator
Bergmann et al (2020)[37]	Germany	1	2016-2018	Adults with pain due to TMD and sleep bruxism	Full-occlusion biofeedback splint (n=20)	Adjusted occlusal splint (n=21)

TMD: temporomandibular disorder.

Table 11. Summary of Key Randomized Controlled Trial Results

Study	Total duration of bruxism events per hour	Number of bruxism bursts per hour	Pain symptoms
Bergmann et al (2020)[37,]	*Mean change from baseline in seconds of bruxism per hour*	*Mean change from baseline in number of bursts per hour*	*Percent change in general pain perception from baseline at 3 months*
Full-occlusion biofeedback splint	At 1 month: -5.1 seconds At 3 months: -5.2 seconds	At 1 month: -2.4 At 3 months: 2.2	-50%
Adjusted occlusal splint	At 1 month: 40.1 seconds At 3 months: 11.5 seconds	At 1 month: 4.5 At 3 months: 1.8	7%
p-value	At 1 month: 0.014 At 3 months: 0.060	At 1 month: 0.281 At 3 months: 0.730	0.017

Table 12. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Bergmann et al (2020)[37]				5. Clinically significant difference in number/duration of bruxism events not defined	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 13. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Bergmann et al (2020)[37]		1, 2. Patients, therapists, and analysts were not blinded		1. Several patients in each group had corrupt data due to technical problems with the splints and were classified as lost to follow-up for that reason	1. Power calculations not reported.	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Sleep Bruxism

For individuals with sleep bruxism who receive biofeedback, the evidence includes 2 systematic reviews and an RCT published after the review. One systematic review identified 7 randomized and nonrandomized studies using biofeedback techniques, and the most recent systematic review identified 6 additional studies. Studies were generally small, used different techniques, measured different outcomes, and were assessed as having either moderate or

high risk of bias. Two studies reported the number of bruxism episodes per hour and a pooled analysis of these studies showed no significant differences between biofeedback groups and control groups. An RCT published after the reviews tested a full-occlusion biofeedback splint in 41 patients with sleep bruxism and temporomandibular disorder. The trial found that, compared to an adjusted occlusal splint, the biofeedback splint allowed for greater reductions in pain after 3 months of treatment. However, no significant differences in sleep bruxism episodes were observed.

Tinnitus

Review of Evidence

Randomized Controlled Trials

An RCT by Weise et al (2008) investigated the efficacy of a biofeedback-based cognitive-behavioral treatment for tinnitus in Germany.[38] Tinnitus patients (N=130) were randomly assigned to an intervention or a waiting-list control group. Treatment consisted of 12 sessions of a biofeedback-based behavioral intervention for over 3 months. 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 scores. Patients in the waiting-list group participated in the treatment after the intervention group had completed the treatment. Results showed improvements in tinnitus annoyance, diary ratings of loudness, feelings of controllability, changes in coping cognitions, and changes in depressive symptoms in the control group. The TQ total score had a potential range of 0 to 84. The preassessment mean in the TQ total score was 54.7, and the post-assessment mean was 32.5.

Section Summary: Tinnitus

For individuals with tinnitus who receive biofeedback, the evidence includes a single RCT. Treatment consisted of a biofeedback-based behavioral intervention over a 3-month period. The treatment group experienced improvements in tinnitus annoyance, loudness ratings, controllability, coping cognitions, and depressive symptoms. Additional studies are needed to confirm the results of this single trial.

Summary of Evidence: Miscellaneous Indications

For individuals with anxiety disorders who receive biofeedback, the evidence includes two systematic reviews and two randomized controlled trials (RCTs) published after the review. Relevant outcomes are symptoms, functional outcomes, and quality of life (QOL). A systematic review on heart rate variability (HRV) biofeedback (HRVB) and an RCT on diaphragmatic breathing relaxation reported the positive effects of these treatments on anxiety. However, the trials in the systematic review had small sample sizes (median, 14 participants) and study quality was generally poor. Additional limitations included improper randomization, allocation concealment, and inadequate descriptions of randomization or missing data. The other RCT did not find a significant effect of biofeedback, possibly due to lack of power. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with asthma who receive biofeedback, the evidence includes a systematic review of 3 RCTs and 2 RCTs published after the review. Relevant outcomes are symptoms, functional outcomes, and QOL. Each RCT used a different biofeedback technique, which provided patients with information on carbon dioxide, heart rate, and respiratory sinus arrhythmia. While the trials reported improvements in each parameter for which the patients received biofeedback, the improvements did not impact clinical outcomes such as medication use and forced expiratory volume. However, the results of one RCT suggested that biofeedback has promise as a protective approach to aiding lung function and reducing stress-induced asthma exacerbation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with Bell palsy who receive biofeedback, the evidence includes a systematic review of 4 RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. The RCTs evaluated the efficacy of adding a mirror and/or electromyography (EMG) biofeedback to facial exercises. The sample sizes were small, and there was heterogeneity across techniques used and length of treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with depression who receive biofeedback, the evidence includes a systematic review and its 2017 update and 2 small RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, and QOL. The review and its update only identified 3 dissertations assessing the use of biofeedback for depression. One RCT found that respiratory and heart rate biofeedback plus usual care reduced Beck Depression Inventory scores compared to usual care alone, while the other found that respiratory sinus arrhythmia biofeedback plus usual care was associated with greater improvements in Hamilton Depression Rating Scale scores compared to usual care alone; however, these trials were limited by open-label designs, short follow-up periods, and small sample sizes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with hypertension who receive biofeedback, the evidence includes 2 systematic reviews and 2 RCTs published after the review. Relevant outcomes are symptoms, functional outcomes, and QOL. The systematic review identified 36 RCTs, though sample sizes were small and overall study quality was poor. Various biofeedback techniques were used: thermal, galvanized skin response, pulse wave velocity, and heart rate variability. Results across trials did not consistently show a benefit of biofeedback. Conclusions were limited due to the shortage of studies isolating the effect of biofeedback, the generally poor quality of trials, and heterogeneity across interventions used. The other systematic review was smaller (20 RCTs) but did find a significant effect of biofeedback on both systolic and diastolic blood pressure. The Mengden 2023 RCT demonstrated an acute change in blood pressure after a 10-min biofeedback session, but no longer term effects were demonstrated over the course of a week. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with motor dysfunction after stroke who receive biofeedback, the evidence includes systematic reviews and RCTs published after the systematic reviews. Relevant outcomes are symptoms, functional outcomes, and QOL. One systematic review identified 18 high-quality trials using the following biofeedback techniques: weight distribution on a platform sensor, muscle activity from electromyography, linear gait parameters, and joint angle from a goniometer. Feedback was visual, auditory, or both. Outcome measures primarily assessed motor activity in research settings, rather than clinical outcomes such as rates of falls or the ability to perform activities of daily living. Pooled effects showed improvements in motor function in the short term. The evidence is limited due to the variability in type, duration, and intensity of the interventions and lack of long-term outcomes. The largest available studies published since the systematic reviews found no differences between biofeedback-assisted rehabilitation and conventional rehabilitation in terms of their impact on gait speed, balance, activities of daily living, fall rate, and return to work. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with motor dysfunction after lower-limb injury or surgery who receive biofeedback, the evidence includes two systematic reviews. Relevant outcomes are symptoms, functional outcomes, and QOL. One systematic review identified 4 RCTs evaluating the use of EMG biofeedback in patients undergoing postinjury knee rehabilitation. Sample sizes were small, with half of the trials reporting significant benefits of biofeedback and the other half reporting no difference between study groups. The other systematic review identified 6 RCTs evaluating the use of EMG biofeedback in patients undergoing postsurgical knee rehabilitation. Biofeedback was associated with better range of motion outcomes in a meta- analysis of data from 5 RCTs, but was not associated with a significant benefit in terms of pain or physical functioning The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with multiple sclerosis who receive biofeedback, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. One trial used vibrotactile biofeedback and the other provided patients with breathing rate and muscle tension biofeedback. The sample sizes were small, with no statistically significant differences between the biofeedback groups and control groups. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with orthostatic hypotension due to spinal cord injury who receive biofeedback, the evidence includes a systematic review, which included a case series and a case report. Relevant outcomes are symptoms, functional outcomes, and QOL. The case series and case report collectively provided information on 3 patients given visual and auditory feedback. Patients were able to raise their systolic blood pressure by an average of 39%. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who need pain management during labor who receive biofeedback, the evidence includes a systematic review of 4 RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. A Cochrane review graded the 4trials as having a high risk of bias due to unclear descriptions of blinding and randomization methods. Due to the heterogeneity in biofeedback methods and outcomes measured, pooled analyses could not be performed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with posttraumatic stress disorder (PTSD) who receive biofeedback, the evidence includes a 2014 systematic review and its 2017 update, and a 2024 systematic review. Relevant outcomes are symptoms, functional outcomes, and QOL. The systematic review included an RCT, a nonrandomized study, and 2 case series. The studies had small sample sizes and inconsistent results. The reviewers rated the evidence a grade C for conflicting scientific evidence. The 2017 systematic review update included 2 new RCTs, 1 of which demonstrated a faster decrease of PTSD symptoms with biofeedback and cognitive behavioral therapy (CBT) compared to CBT alone. However, the small sample size was a limitation. The other RCT found no differences between biofeedback and other treatment modalities. The 2024 systematic review found a moderate effect of biofeedback but none of the included studies had a control group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are susceptible to preterm birth who receive biofeedback, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, and QOL. In the RCT, women in the treatment group received heart rate variability biofeedback. Patients receiving the treatment experienced a decrease in perceived chronic stress, but there was no significant difference in the number of preterm births, gestational duration, or birth weight. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with Raynaud disease who receive biofeedback, the evidence includes a systematic review. Relevant outcomes are symptoms, functional outcomes, and QOL. The systematic review identified 5 RCTs using biofeedback techniques. Pooled analysis was performed on 4 of these trials. The reduction in the frequency of attacks was significantly lower in the sham control group. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with sleep bruxism who receive biofeedback, the evidence includes 2 systematic reviews and an RCT published after the review. Relevant outcomes are symptoms, functional outcomes, and QOL. One systematic review identified 7 randomized and nonrandomized studies using biofeedback techniques, and the most recent systematic review identified 6 additional studies. Studies were generally small, used different techniques, measured different outcomes, and were assessed as having either moderate or high risk of bias. Two studies reported the number of bruxism episodes per hour and a pooled analysis of these studies showed no significant differences between biofeedback groups and control groups. An RCT published after the reviews tested a full-occlusion biofeedback splint in 41 patients with sleep bruxism and temporomandibular disorder. The trial found that, compared to an adjusted occlusal splint, the biofeedback splint allowed for greater reductions in pain after 3 months of treatment. However, no significant differences in sleep bruxism episodes were observed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with tinnitus who receive biofeedback, the evidence includes a single RCT. Relevant outcomes are symptoms, functional outcomes, and QOL. Treatment consisted of a

biofeedback-based behavioral intervention over a 3-month period. The treatment group experienced improvements in tinnitus annoyance, loudness ratings, controllability, coping cognitions, and depressive symptoms. Additional studies are needed to confirm the results of this single trial. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

Urinary Incontinence

In response to requests, Blue Cross Blue Shield Association received input from 4 physician specialty societies and 2 academic medical centers while this policy was under review in 2009. Clinical input varied. Several reviewers commented on the lack of data (e.g., those who cannot do pelvic exercises) as well as the inability to separate in the available literature the contribution of biofeedback to overall outcomes in many studies.

Headache

In response to requests, Blue Cross Blue Shield Association received input through 3 physician specialty societies and 3 academic medical centers (4 inputs) while this policy was under review in 2009. Additional comments were received in 2020. Input considered biofeedback to be a reliable and appropriate nonpharmacologic option for the treatment of headaches.

PRACTICE GUIDELINES AND POSITION STATEMENTS

Urinary Incontinence

American College of Obstetricians and Gynecologists and the American Urogynecologic Society

The American College of Obstetricians and Gynecologists and the American Urogynecologic Society issued a practice bulletin (issued 2015; reaffirmed 2022) on urinary incontinence in women.[1] The practice bulletin states, "Pelvic muscle exercises may be used alone or augmented with bladder training, biofeedback, or electrical stimulation".

American Urological Association et al

In their guidelines on treatment of stress urinary incontinence in women, the American Urological Association and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (2017) recommended offering several treatment options including pelvic floor muscle training with biofeedback: “Pelvic floor muscle training and incontinence pessaries are appropriate for patients interested in pursuing therapy that is less invasive than surgical intervention. Pelvic floor physical therapy can be augmented with biofeedback in the appropriate patient. The patient must be willing and able to commit to regularly and consistently performing pelvic floor training for this to be successful.”[2] A 2023 update to these guidelines which focused on surgical treatment of stress urinary incontinence include a recommendation for pelvic floor exercises with or without biofeedback as a nonsurgical option.[3]

The 2024 American Urological Association/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction guideline on overactive bladder includes biofeedback as an example of non-invasive therapies.[4] Although they make no specific recommendations for biofeedback, they state, "Clinicians may offer select non-invasive therapies to all patients with OAB." However, they caution, "While safety profiles are excellent across modalities, with few adverse effects and a high risk-benefit ratio, all non-invasive therapies do not have equivalent efficacy and the evidence base is highly variable. Most non-invasive therapies require long-term patient compliance to maintain a durable effect and patients should be counselled as such before embarking on a course of a potentially lifelong therapy."

The American Urological Association/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction Guideline (2019; amended 2024) on treating incontinence after prostate treatment states that the randomized controlled trial that were assessed differed on the regimen of pelvic floor muscle training, with some studies including biofeedback or electrical stimulation.[5] Guideline Statement 16 recommends pelvic floor muscle exercises or pelvic floor muscle training, but biofeedback is not mentioned as part of the treatment.

American College of Physicians

The American College of Physicians (2014) published clinical practice guidelines on nonsurgical management of urinary incontinence in women.[6] The guidelines were based on literature published through December 2013. The College concluded that low-quality evidence showed pelvic floor muscle training (PFMT) with biofeedback using a vaginal electromyography probe increased continence compared to no active treatment and that high-quality evidence showed this combination of treatments improved urinary incontinence symptoms compared to no active treatment. The guidelines did not compare PFMT alone and PFMT plus biofeedback.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2019) updated its 2006 guidance on the management of urinary incontinence in women.[7] Recommendations on biofeedback included: “do not use perineometry or pelvic floor electromyography as biofeedback as a routine part of pelvic floor muscle training” and “electrical stimulation and/or biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy”.

Canadian Urological Association

In 2012, the Canadian Urological Association issued guidelines on treatment of adult urinary incontinence.[8] The guidelines made the following conclusions on the use of biofeedback for postprostatectomy incontinence and stress incontinence, respectively:

“Preoperative biofeedback-assisted behavioural training can shorten the time to regain continence postoperatively and reduce the prevalence of severe incontinence 6 months after the procedure (level of evidence 2, grade B)…. Postoperative … biofeedback does not appear to improve continence outcomes compared with PFMT (level of evidence 2, grade B).

“The benefit of biofeedback is unknown (grade B).”

Fecal Incontinence or Constipation

American Neurogastroenterology and Motility Society & European Society of Neurogastroenterology and Mobility

In 2015, the American Neurogastroenterology and Motility Society and the European Society of Neurogastroenterology and Mobility jointly published a consensus guideline on biofeedback therapy for anorectal disorders.[1] The guideline 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

In 2015, the American Society of Colon and Rectal Surgeons (ASCRS) updated its guideline on treatment of fecal incontinence.[2] Those guidelines were updated in 2023.[3] Biofeedback is no longer considered first line, but may still be considered for patients with fecal incontinence (conditional recommendation, low quality of evidence).

In 2024, ASCRS published a guideline on the evaluation and management of chronic constipation.[4] The guideline state that biofeedback therapy is a first-line treatment for symptomatic pelvic floor dyssynergia (strong recommendation, moderate quality of evidence).

American Gastroenterological Association

In 2013, the American Gastroenterological Association updated its position statement on constipation. The statement included the following on biofeedback: “Pelvic floor retraining by biofeedback therapy rather than laxatives is recommended for defecatory disorders (Strong Recommendation, High-Quality Evidence).”[5]

In 2017, the AGA published an expert review on surgical interventions and device-aided therapy for the treatment of fecal incontinence and defecation disorders.[6] The Association stated that surgical options may be considered in patients with fecal incontinence and defecation disorders, but only after conservative therapy has failed. Examples of conservative therapies include dietary modification, fiber supplements, bowel training programs, pelvic floor exercises, medications, or biofeedback.

National Institute for Clinical Excellence

In 2017, NICE updated its guidance on constipation in children and young people.[7] The guidance indicated that biofeedback should not be used for ongoing treatment.

In 2007, the NICE issued guidance on fecal incontinence in adults; the guidance stated the following on biofeedback: “The evidence we found did not show biofeedback to be more

effective than standard care, exercises alone, or other conservative therapies. The limited number of studies and the small number of participants in each group of the studies make it difficult to come to any definitive conclusion about its effectiveness."[8]

American College of Gastroenterology

In 2021, the American College of Gastroenterology (ACG) published a guideline on the management of benign anorectal disorders.[9] The guideline notes: "We recommend that instrumented anorectal biofeedback therapy should be used to manage symptoms in DD [defecation disorder] (strong recommendation; minimal risk of harm; quality of evidence: moderate)." Furthermore, the guideline notes the following key concepts related to biofeedback in the setting of DD:

- "Biofeedback should involve 4–6 sessions with well-trained therapists aimed at normalizing rectoanal coordination, ensuring good rectal pressure on strain, sensory retraining, and balloon expulsion retraining.
- Baseline ARM [anorectal manometry] and balloon expulsion is useful to predict the outcome and guide biofeedback therapy
- Defecography (MR [magnetic resonance] or barium) may be indicated in patients with DD who fail conservative therapy and biofeedback."

Headache

American Headache Society

In 2021, the American Headache Society released a consensus statement on integration of new migraine treatments into clinical practice, including biobehavioral therapies (cognitive behavioral therapy, biofeedback, and relaxation).[1] According to the consensus statement, "biobehavioral therapies have Grade A evidence supporting their use as preventive treatments in patients with migraine." The statement notes that biobehavioral therapies are particularly suited for the following individuals:

- Prefer nonpharmacologic interventions
- Have inadequate response, poor tolerance, or medical contraindications to specific pharmacologic treatments
- Are pregnant, lactating, or planning to become pregnant
- Have a history of acute medication overuse or medication-overuse headache
- Exhibit significant stress or deficient stress-coping skills
- Have high migraine-related disability, and/or low health-related quality of life, and/or comorbidities.

Association for Applied Psychophysiology and Biofeedback

In 2013, the Association for Applied Psychophysiology and Biofeedback issued standards for performing biofeedback.[2] The standards state that biofeedback for the treatment of migraine and tension headache has been validated as being safe and effective for these particular conditions and that biofeedback is not used alone as a diagnostic tool or treatment; rather, it is an adjunctive tool to be used in combination with other standard interventions.

Chronic Pain

American College of Occupational and Environmental Medicine

In 2020, the American College of Occupational and Environmental Medicine updated their guideline on noninvasive and minimally invasive management of low back disorders. [1] The role of biofeedback is not addressed in this updated guideline.

American Society of Anesthesiologists & American Society of Regional Anesthesia and Pain Medicine

In 2010, practice guidelines by the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine suggested that “cognitive behavioral therapy, biofeedback, or relaxation training: These interventions may be used as part of a multimodal strategy for patients with low back pain, as well as for other chronic pain conditions.” [2]

U.S. Department of Veterans Affairs and U.S. Department of Defense

In 2022, the U.S. Department of Veterans Affairs and U.S. Department of Defense updated their guideline on the diagnosis and treatment of low back pain.[3] The guideline recommends several nonpharmacologic therapies for chronic low back pain (eg, CBT and/or mindfulness-based stress reduction, progressive relaxation, exercise including yoga, pilates, and tai chi) but does not address the role of biofeedback.

North American Spine Society

In 2020, the North American Spine Society published a guideline for the diagnosis and treatment of low back pain.[4] Although nonpharmacologic therapies are addressed in this guideline, the specific role of biofeedback for low back pain is not addressed.

Miscellaneous Indications

American Psychiatric Association

The American Psychiatric Association (APA) guidelines on the treatment of major depressive disorder (MDD) have not been updated since 2010, and the APA guidelines on acute stress disorder and posttraumatic stress disorder have not been updated since 2004. These guidelines are classified as "legacy guidelines" by the organization, meaning that they can no longer be assumed to be current. The APA (2010) guidelines on the treatment of patients with MDD did not list biofeedback as a potential treatment.[1]

In 2004, the APA guidelines on the treatment of patients with acute stress disorder and posttraumatic stress disorder mentioned that biofeedback may be used to augment relaxation techniques.[2] The guidelines suggested that biofeedback could provide patients with instantaneous feedback on physiological measures such as blood flow and muscle contraction, which enables patients to exert some degree of control over those measures to relieve tension and anxiety.

American Psychological Association

As of September 2024, the American Psychological Association has made no recommendations regarding the use of biofeedback for depression, anxiety, or PTSD.

American Academy of Neurology
As of September 2024, the American Academy of Neurology has made no recommendations regarding the use of biofeedback for multiple sclerosis, Bell palsy, or orthostatic hypotension due to spinal cord injury.

American College of Cardiology
In 2017, the American College of Cardiology et al guidelines on hypertension in adults states that "behavioral therapies, including....biofeedback, lack strong evidence for their long-term BP-lowering effect."[3]

American Heart Association and American Stroke Association
In 2016, the American Heart Association and the American Stroke Association guidelines on adult stroke rehabilitation and recovery state that the usefulness of biofeedback during gait training in patients after stroke is uncertain.[4]

American College of Obstetricians and Gynecologists
As of September 2024, the American College of Obstetricians and Gynecologists has made no recommendations on the use of biofeedback for pain management during labor or to prevent preterm birth.

Global Initiative for Asthma
As of September 2024, the Global Initiative for Asthma guidelines make no recommendations regarding the use of biofeedback for asthma.[5]

U.S. Department of Veterans Affairs/Department of Defense
As of September 2024, clinical practice guidelines from the U.S. Department of Veterans Affairs and the Department of Defense do not make recommendations on the use of biofeedback for PTSD, hypertension, or asthma.[6] The 2022 guidelines for the management of MDD state that 'for patients with MDD, there is insufficient evidence to recommend for or against the addition of biofeedback." [7] Similarly, the 2024 guidelines for the management of stroke state that there is insufficient evidence to recommend for or against biofeedback to improve motor function in patients with stroke.[8]

Government Regulations
National:

NCD - BIOFEEDBACK Therapy (30.1), this is a longstanding national coverage determination. The effective date of this version has not been posted.

Indications and Limitations of Coverage

Biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education of specific, muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm or weakness, and more conventional treatments (heat, cold, massage, exercise, and support) have not been successful. This therapy is not covered for the treatment of ordinary muscle tension states or for psychosomatic conditions.

NCD for Biofeedback Therapy for the Treatment of Urinary Incontinence (30.1.1), 7/1/2001

Indications and Limitations of Coverage
This policy applies to biofeedback therapy rendered by a practitioner in an office or other facility setting.

Biofeedback is covered for the treatment of stress and/or urge incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training. Biofeedback is not a treatment, per se, but a tool to help patients learn how to perform PME. Biofeedback assisted PME incorporates the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor musculature and to assist patients in the performance of PME.

A failed trial of PME training is defined as no clinically significant improvement in urinary incontinence after completing 4 weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.

Contractors may decide whether or not to cover biofeedback as an initial treatment modality. Home use of biofeedback therapy is not covered.

Local:

Wisconsin Physicians Service Insurance Corporation
Local Coverage Determination, Biofeedback (L31070) - Retired

Indications and Limitations of Coverage and/or Medical Necessity

Biofeedback training is a type of behavioral technique by which information about a normally unconscious physiologic process is presented to the patient and is demonstrated by a signal to educate the patient for an optimal muscle response. Retraining typically includes a process by which the patient is evaluated in the office setting and taught how to utilize the affected muscle group therapeutically. The muscle group involved is monitored with a device where the patient can observe, through visual or auditory means, the muscle group movements. Where there is abnormal or absent muscle movements, the patient can be reinforced with observed changes with optimal muscle movements. The patient will then practice the learned techniques. The patient will continue to practice at home (or other non-office setting) the optimal muscle movements utilizing the training guide.

A. Biofeedback training is typically performed in situations where a patient has had other therapies that have been unsuccessful or contraindicated. Other therapies include, but are not limited to,
1. Pharmacological treatments,
2. Physical therapy treatment, and
3. Exercise training.

4. Occupational Therapy.
5. Speech Therapy

B. Biofeedback training has been proven successful when all of the following criteria exist:
1. The patient is motivated to actively participate in the treatment plan, including being responsive to the care plan requirements (e.g., practice and follow-through at home);
2. The patient must be capable of participating in the treatment plan (physically as well as intellectually);
3. The patient's condition is appropriately treated with biofeedback (e.g., pathology does not exist preventing success of the training).

C. Medicare coverage will be allowed for medically necessary biofeedback training when performed with the continuous presence of a physician or by a qualified non-physician practitioner. Continuous presence requires one-on-one face-to-face involvement with the patient and practitioner during training.

D. There should be a plan of care certified by the Medicare attending/ordering physician/provider, which contain the goals of therapy, the exercise prescription, and measurable objectives.

E. Biofeedback Training (CPT code 90901) is considered medically necessary when other treatments have failed or are contraindicated and it is performed for one of the indications listed in this LCD.

F. Biofeedback training anorectal, including EMG and/or manometry (CPT code 90912, 90913) is covered for anal muscle abnormalities of spasticity, incapacitating muscle spasm, dyssynergic, and/or muscle weakness.

a. Anal spasms (ICD-9 code 564.6)
b. Detrusor sphincter dyssynergia (596.55)
c. Fecal incontinence (ICD-9 code 787.60-787.63)
d. Slow Transit Constipation (ICD-9 564.01)
e. Outlet Dysfunction Constipation (ICD-9 564.02)

G. Biofeedback for pelvic floor retraining for urinary incontinence (90912, 90913) is covered if performed with the aid of EMG and/or electrical stimulation techniques when other treatments have not been effective or contraindicated, for the following conditions:

a. Intrinsic urethral sphincter deficiency (ICD-9 code 599.82)
b. Stress incontinence, female (ICD-9 codes 625.6)
c. Urinary incontinence, unspecified (ICD-9 codes 788.30)
d. Urge Incontinence (ICD-9 code 788.31)
e. Stress incontinence, male (ICD-9 code 788.32)
f. Mixed incontinence (ICD-9 code 788.33)

H. Muscle Spasms (728.85) is covered only when the medical record contains documentation that indicates the site and that the spasms are incapacitating.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated

and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Neurofeedback
- Psychophysiological Therapy (Biofeedback) for the Treatment of TMJ Disorders (Retired)
- Psychophysiological Therapy for Treatment of Nocturnal Enuresis (Retired)

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Urinary Incontinence

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Miscellaneous Indications

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Government Regulations

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3. Wisconsin Physicians Service (WPS), “Biofeedback,” WPS Local Medical Review Policy, L31070, contractor determination number PHY-066, original effective date 4/15/11, original determination ending date 5/1/12. Retired.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through December 27, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/30/04	9/30/04	10/14/04	Joint policy established
2/28/05	2/28/05	2/28/05	Routine maintenance; added chronic constipation to covered conditions
7/1/06	5/2/06	3/10/06	Routine maintenance
11/1/07	8/21/07	10/22/07	Routine maintenance
1/1/09	10/13/08	10/13/08	Maintenance; pediatric indications added to policy
3/1/10	12/8/09	12/8/09	Routine maintenance; policy title changed from Biofeedback for Urinary and Fecal Incontinence to Biofeedback.
3/1/12	12/13/11	12/21/11	Routine maintenance
3/1/15	12/12/14	12/29/14	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
7/1/17	4/18/17	4/18/17	Routine maintenance Migraine and tension-type headache added as covered indications.
1/1/18	10/19/17	10/19/17	Routine maintenance Revised rationale
1/1/19	10/16/18	10/16/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance; Urinary Incont: Ref 12 added.
5/1/21	2/16/21		Routine maintenance; Fecal Incont or Constipation: Ref 5, 7 added, Headache: Ref 7 added, Chronic Pain: Ref 29, 30, 31, MISC Indications: Ref 16, 17, 32, 38, 39 added.
5/1/22	2/17/22		Routine maintenance
5/1/23	2/21/23		Routine maintenance Vendor Review: NA (ky)

5/1/24	2/20/24		Routine maintenance Vendor Review: NA (ky)
5/1/25	2/18/25		Routine maintenance Vendor Review: NA (ky)

Next Review Date: 1st Qtr, 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BIOFEEDBACK

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria applies.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service. *Exception: If BCN65 member has an "exact-fill" option, BCN may cover the service even if Medicare does not.*

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.