Clinical Practice Guideline: **Biofeedback**

Date of Implementation: **November 15, 2018**

Product: **Specialty**

GUIDELINES

<u>Medically Necessary</u>

Biofeedback performed by a licensed healthcare professional is considered medically necessary for ANY of the following conditions*:

- Chronic constipation with dyssynergic defecation (adults only).
- Fecal incontinence for patients with:
    - Some degree of rectal sensation; and
    - Ability to contract the sphincter voluntarily; and
    - Failure/intolerance/contraindication of treatment with dietary changes, devices or drugs.
- Stress, urgency, mixed, or overflow urinary incontinence when there is failure/intolerance/contraindication of other nonpharmacologic treatment (e.g., bladder training and/or pelvic floor muscle training [PFMT]) (children and adults)
- Migraine and tension headaches (children and adults).
- 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, support) have not been successful.
    - This therapy is not covered as medically necessary for treatment of ordinary muscle tension states or for psychosomatic conditions.
- Refractory levator ani syndrome (e.g., proctalgia fugax, chronic anal pain syndrome, anal spasm) with dyssynergic defecation when:
    - Condition is not neurological or disease based.
    - Failure/intolerance/contraindication of conservative treatment including:
        - High-fiber diet;
        - Withdrawal of drugs that cause constipation (e.g., calcium channel blockers, narcotics) or diarrhea (e.g., antibiotics, quinidine, theophylline);
        - Perineal strengthening exercises;
        - Rectal massage;
        - Warm baths; and
        - Drug therapy (e.g., muscle relaxants, non-narcotic analgesics, and sedatives).

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To QOC for review and approval 07/20/2023
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*NOTES:

- Patients must be cognitively intact and willing and motivated to learn and practice the specific tasks needed to correct/improve their condition.
- The patient's care plan requires co-management with other appropriate health care providers.
- There should be a written treatment plan which must include all of the following information:
  - The specific diagnosis/conditions to be treated;
  - Long- and short-term goals;
  - Measurable objectives;
  - The time frame and the frequency of treatment in which the goals and objectives will be achieved.

Unproven

Biofeedback for ANY other indication is considered unproven, including but not limited to:

- As a rehabilitation modality for spasmodic torticollis, spinal cord injury, or following knee surgeries
- Attention deficit hyperactivity disorder (ADHD)
- Autism
- Bell's palsy (idiopathic facial paralysis)
- Cardiovascular diseases (e.g., heart failure)
- Chemotherapy-induced peripheral neuropathy
- Childhood apraxia of speech
- Chronic fatigue syndrome
- Chronic pain (e.g., back pain, fibromyalgia, neck pain) other than migraine and tension headache
- Epilepsy
- Essential hypertension (e.g., by means of the RESPeRATE Device)
- Facial pain
- Functional dysphonia
- Home Biofeedback (for any indication)
- Improvement of anorectal/bowel functions after sphincter-saving surgery for rectal cancer
- Neurogenic bladder
- Non-neuropathic voiding disorders
- Labor pain
- Prophylaxis of medication overuse headache and pediatric migraine
- Raynaud's disease/phenomenon
- Rheumatoid arthritis
- Sleep bruxism

- Spasticity secondary to cerebral palsy
- Temporomandibular joint (TMJ) syndrome
- Toe-out gait modification/retraining in people with knee osteoarthritis
- Vaginismus
- Vulvodynia

The following is considered not medically necessary and/or unproven:

- Electroencephalography (EEG) biofeedback or neurofeedback

Covered When Medically Necessary

CPT®* Codes	CPT®* Code Description
90901	Biofeedback training by any modality
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)

DESCRIPTION

The three most commonly used forms of biofeedback therapy are: (1) electromyography (EMG), which measures muscle tension; (2) thermal biofeedback, which measures skin temperature; and (3) neurofeedback or electroencephalography (EEG), which measures brain wave activity. Various forms of biofeedback appear to be effective for a narrow range of health problems. This guideline includes various indications or proposed indications for biofeedback (EMG and/or thermal), electroencephalography (EEG) biofeedback or neurofeedback, and in-home biofeedback devices.

GENERAL BACKGROUND

Biofeedback therapy provides visual, auditory or other evidence of the status of certain body functions so that a person can exert voluntary control over the functions, and thereby alleviate an abnormal bodily condition. Biofeedback therapy often uses electrical devices to transform bodily signals indicative of such functions as heart rate, blood pressure, skin temperature, salivation, peripheral vasomotor activity, and gross muscle tone into a tone or light, the loudness or brightness of which shows the extent of activity in the function being measured. It emphasizes relaxation, enhancement of muscle contraction and/or stress-reduction. Biofeedback is considered an alternative medicine technique (National Center for Complementary and Alternative Medicine [NCCAM], 2017; Holroyd et al., 2003; Karmody, 2003; Kiresuk et al., 2005).

There are several different types of biofeedback. The biofeedback modality selected for therapy depends on the condition to be treated. EMG biofeedback measures muscle tension and is proposed for the treatment of chronic muscle stiffness, injury and pain (e.g., neck and back pain); headaches, asthma, incontinence; and intestinal symptoms. Thermal or temperature biofeedback measures skin temperature and is proposed for the treatment of circulatory disorders, such as headaches, hypertension, and Raynaud's phenomenon. Galvanic skin response (GSR) biofeedback, also called electrodermal response (EDR), electrodermal activity (EDA), skin conductance response (SCR) or skin conductance level (SCL) biofeedback, measures electrical conductance in the skin associated with sweat gland activity and perspiration. GSR is proposed for the treatment of anxiety disorders and phobias. Another form of biofeedback is electroencephalogram (EEG) biofeedback, also called neurofeedback, brainwave biofeedback or neurotherapy, which measures alpha (associated with relaxation and meditation) and theta (associated with focused attention) brainwave activity. It is proposed to counterbalance genetic and environmental tendencies by learning to alter brain wave patterns. EEG biofeedback has been proposed for the treatment of multiple conditions including insomnia, attention deficit hyperactivity disorder (ADHD), dyslexia, anxiety disorders, autism spectrum disorders, epilepsy, addictions, tinnitus, brain injury, depression, learning disabilities, pervasive developmental delay/intellectual disability, fibromyalgia, dyslexia. However, the evidence in the published peer-reviewed scientific literature does not support the efficacy of EEG biofeedback.

Forms of biofeedback have been in use in physical therapy for more than 50 years, where it is beneficial in the management of neuromuscular disorders. Biofeedback techniques have shown benefit when used as part of a physical therapy program for people with motor weakness or dysfunction after stroke, after orthopedic surgery, or due to other neuromuscular diseases. These methods are getting better at training for complex task-oriented activities like walking and grasping objects as technology continues to advance. Aside from neuromuscular retraining, the most common use for biofeedback is to help with chronic symptom management due to anxiety, pain, and urinary and fecal incontinence. These techniques focus on managing the overactive sympathetic response and coordinating muscle activity in gastrointestinal and genitourinary tracts. Biofeedback techniques are generally regarded as safe and free of side effects. For this reason, they are incorporated into treatment plans despite lacking strong evidence to support their benefits (Malik and Dua, 2021).

Although there are numerous biofeedback devices available for home use, biofeedback should be performed in a clinical setting with the continuous presence of the 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. Qualified non-physician practitioners include physical and occupational therapists in independent practice, Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists. Examples of home devices include: StressEraser® (Helicor, Inc., New York, NY) for mind and body relaxation; BrainMaster (BrainMaster Technologies, Inc., Oakwood Village, OH) EEG biofeedback devices; GSR/Temp2XTM (Biofeedback Instrument Corp., New York, NY) temperature biofeedback system; and RESPeRate (Intercure Ltd., Lod, Israel) which uses therapeutic paced breathing to lower blood pressure.

Urinary Incontinence

Urinary incontinence (UI) affects people of all ages, especially elderly women. Among adults, there are 4 prevalent types of UI: (1) stress incontinence (closure problem), (2) urge incontinence (storage problem), (3) overflow incontinence, and (4) mixed stress and urge incontinence. In women, stress incontinence is generally caused by an incompetent urethral mechanism which arises from damage to the sphincter(s) or weakening of the bladder neck support that typically occurred during childbirth. In men, stress incontinence is usually a consequence of operations for benign prostatic hypertrophy (BPH) or prostate cancer. Urge incontinence is usually associated with an over-activity of the detrusor muscle. When the involuntary contraction of the detrusor muscle is associated with a neurological deficit, it is known as detrusor hyperreflexia. On the other hand, when detrusor over-activity is not associated with any neurological deficit, it is labeled as detrusor instability (unstable bladder). Overflow incontinence may be due to an underactive detrusor muscle or obstruction of the urethra. In men, overflow incontinence associated with obstruction is usually due to prostatic hyperplasia. Urethral obstruction in women may occur as a consequence of anti-incontinence operation or severe prolapse of the uterus or relaxation of the anterior vaginal wall with cystocele or cystourethrocele.

Over 20 million women experience stress, urgency, or mixed incontinence (Wu et al., 2009). There are limited non-surgical treatment options available for women with stress, mixed, and urgency UI and most require the involvement of skilled healthcare professionals, which may be limited in number. Additionally, geographical access can be challenging for first line treatment of UI. Studies estimate that at least 50% of women do not seek care for UI (Morrill et al., 2007; Berger et al., 2011). Disparities specific to urinary incontinence exist relative to race and ethnicity, education, socioeconomic status, knowledge of UI and care, access to care, and treatment (Brown and Simon, 2021). These factors create barriers to health equity. Also inherent in these disparities is the concept that certain populations may be structurally vulnerable to disparate health outcomes because these groups experience individual patient and system mismatches. A few vulnerable groups identified by Brown and Simon (2021) relative to UI include Black and Native women, individuals with language deficiencies, and rural populations. Access to services (or lack thereof) for UI complicate and impact these structurally vulnerable groups further.

First line treatment of urinary incontinence (stress, urgency, mixed) consists of behavioral treatments with an emphasis on improving quality of life because of their relatively non-invasive and low risk nature. Initial treatment includes lifestyle modifications and pelvic floor muscle exercise (Kegel exercises). Biofeedback is used as an adjunct to pelvic floor muscle exercises. By providing individuals with concurrent feedback on muscle tone, biofeedback is intended to improve the patient's ability to perform pelvic muscle exercises. Augmented versions also use abdominal and perineal EMG recordings to demonstrate improper contraction of abdominal and gluteal muscles. Pelvic muscle exercises can aid in strengthening the voluntary periurethral and pelvic muscles needed to maintain urinary continence since contractions of these muscles raise the urethral pressure. This form of exercise is indicated for women with stress incontinence, men with incontinence following prostatic surgery, and patients with urge incontinence. Depending on the type of UI, patients are taught to contract the pelvic floor muscles, relax the detrusor and the abdominal muscles, and/or contract the sphincters. However, patients are often not compliant with their home pelvic floor muscle training programs, with research demonstrating 25%-33% adherence rates (Moen et al., 2009; Porta Roda et al., 2016; Luo et al., 2021). And for those referred for pelvic floor physical therapy, only 50%-66% attend one visit and even less complete the course of care (~3 visits) (Fullerton et al., 2022; Brown et al., 2020; Shannon et al., 2018; Shannon, Adams et al., 2018). And of those who did perform PFMT, fewer than 25% perform them adequately (Moen et al., 2009).

Biofeedback has been suggested to be useful in teaching patients with UI pelvic muscle exercises because it relays to them whether they are contracting the right muscle(s) and provides positive reinforcements as they acquire the skill during training sessions. Biofeedback has also been suggested to improve compliance and performance of PFMT, but studies are not confirmatory in demonstrating this outcome with standard biofeedback unit use (Hagen et al., 2020; Hagen, Bugge et al., 2020). A newer at-home biofeedback device and remotely delivered program called leva® Pelvic Health System was developed to mitigate some of these issues. This device and program includes motion sensor technology with personal coaching and app technology to help patients train and strengthen their pelvic floor muscles correctly and decrease the symptoms of UI. It is physician-prescribed and does not require physical therapist involvement. Given this, the remotely delivered leva® Pelvic Health System could address potential access issues for patients who cannot easily receive in person treatment.

Fecal Incontinence

Fecal incontinence is the inability to control bowel movements and may involve leakage of stool. Causes of fecal incontinence include severe constipation, chronic diarrhea, overuse of laxatives, damage to the anal sphincter muscles or nerves, anal surgical procedures, spinal cord injury and stroke. Treatment includes changes in dietary habits, pelvic floor muscle exercises and pharmacotherapy. Fecal incontinence (FI) is fairly common in the elderly and children. Dysfunction/abnormality of one or more of many factors, such as mental function, stool volume and consistency, anorectal sensation and reflexes and anal sphincter function, can result in FI. There are various methods for the treatment of FI including behavioral therapies, drug therapies, and surgical intervention. Various biofeedback techniques have also been used in the management of FI. In particular, external anal sphincter (EAS) biofeedback training has been shown to be effective in treating FI. This technique teaches patients to increase the strength of contraction of their EAS in response to rectal distention. There is evidence that biofeedback techniques are safe and effective in the treatment of patients with fecal incontinence, especially those who have some degree of rectal sensation and ability to contract the sphincter voluntarily. Biofeedback training has been demonstrated to restore continence or reduce the frequency of incontinence in patients with fecal incontinence with satisfactory long-term results.

Levator Ani Syndrome

Levator ani syndrome (LAS) is characterized by chronic or recurring episodes of rectal pain or aching in patients with normal structural examinations of the rectum and pelvic floor. Patients with these findings are considered "highly likely" to have LAS if they experience tenderness on palpation of the levator muscles or to have "possible" LAS if they do not experience tenderness. This pain is usually unrelated to a bowel movement, and there appear to be no structural abnormalities or underlying conditions responsible for the symptoms. Though the exact cause is unknown, it is commonly believed that chronic tension of the pelvic floor muscles plays a role in levator ani syndrome. Another theory is that inflammation in the pelvic area is a contributing factor.

People may be at higher risk of levator ani syndrome after childbirth or following surgery on the pelvic area, anus, or spine.

Chronic Constipation

Constipation is one of the most common gastrointestinal complaints in the United States affecting at least 10 % of the general population, and 25 % of the elderly. It is not a disease, but a symptom of various diseases/disorders of mixed etiologies and mechanisms. Constipation is defined as the occurrence of 2 or more of the following symptoms in the previous 12 months (without the use of laxatives): (1) fewer than 3 bowel movements per week, (2) excessive straining during at least 25 % of bowel movements, (3) a feeling of incomplete evacuation after at least 25 % of bowel movements, and (4) passage of hard or pellet-like stool during at least 25 % of bowel movements (Whitehead et al., 1991). Causes for constipation may be colorectal (e.g., malignancy, diverticular disease, pelvic floor dysfunction, and anal fissure), drug-induced (e.g., opioid analgesics, calcium and aluminum-containing antacids, antidiarrheal agents, antidepressants, and antihistamines), metabolic/endocrine (diabetes mellitus, hypothyroidism, hypercalcemia, and pregnancy), and neurogenic (multiple sclerosis, Parkinson's disease, cerebral tumors, and Hirschsprung's disease). Other possible causes include irritable bowel syndrome, inadequate dietary fiber, and psychosocial problems. Pelvic floor outlet obstruction is a functional disorder of evacuation involving the external anal sphincter and pelvic floor voluntary musculature in which the muscles contract, rather than relax. This results in the anal canal being kept tightly closed during straining at attempted defecation. Biofeedback has been used successfully to teach patients with this disorder to relax the sphincter and pelvic floor musculature.

Migraine and Tension-type Headache

It is estimated that 50 million Americans suffer from headache. It is now generally accepted that about 1 in 8 adults in the developed countries has migraine headaches. Women are affected 2 to 3 times more than men. This disorder predominantly affects young adults and the peak incidence is between the age of 25 and 34. There are 2 major types of migraine headaches: (1) migraine with aura (classical migraine) which accounts for 15 to 18 % of all migraine episodes, and (2) migraine without aura (common migraine) which accounts for 80 % of all migraine attacks. Some individuals suffer from both types of migraine at different times. The treatment of choice for frequent migraine sufferers is usually pharmacologic prophylaxis. Avoidance strategies (loud noises, flashing lights, stress, and certain foods) also constitute a very important first line approach in managing migraine. Biofeedback training with or without relaxation techniques have also been shown to be effective in treating migraine and tension headache. In particular, thermal biofeedback training has been shown to be effective in treating migraine headache. This technique teaches patients to increase the temperature of their fingers. Supposedly, dilatation of the peripheral blood vessels in the hand is associated with reduced blood flow in the regions of the supra-orbital and superficial temporal arteries, although the exact mechanism by which thermal biofeedback improves migraine headaches is still unclear. For the management of tension headache, EMG feedback has been employed primarily. Moreover, it has been shown that the combination of thermal and EMG biofeedback has been effective in the control of migraine, tension, and mixed migraine and tension headache. Furthermore, it has been reported that relaxation techniques can produce improvements in headache. Available evidence indicates that biofeedback techniques (thermal, EMG, and temporal blood volume pulse biofeedback), with or without other behavioral therapies (relaxation and cognitive training), are safe and effective methods for the treatment of migraine and tension headache. This therapeutic modality has no side effects and does not preclude other options. Unlike migraine and tension headache, there is a lack of published data concerning the safety and effectiveness of biofeedback in the management of cluster headache.

Before participating in a biofeedback program, patients should be examined by a physician to ensure that their headaches are not due to pathological conditions such as hematomas, aneurysm, brain tumors, brain edema, or diseases of the eye, ear and sinus. First line approaches, including avoidance of precipitating stimuli and pharmacologic prophylaxis, should have been tried and failed.

Neuromuscular Rehabilitation

Typically stroke rehabilitation includes various combinations of range of motion and muscle strengthening exercises, gait and mobility training, and compensatory techniques. Other therapies include neurodevelopmental based methods in which the treatment incorporates neuromuscular re-education techniques where biofeedback may be employed. Among biofeedback techniques employed in neuromuscular rehabilitation, EMG biofeedback is the most common one. It is often utilized by stroke patients for facilitation of contraction (strength) and relaxation of spasticity (inhibition). Electromyographic biofeedback has also been used to treat patients with spasmodic torticollis and patients with muscular atrophy resulting from surgery. The goals of EMG biofeedback in neuromuscular rehabilitation include relaxation of muscles or recruitment of muscles. Relaxation of muscles is performed where muscles are either trained to relax as a consequence of hyperactivity that may be stress or work related or as a result of spasticity caused by central nervous system dysfunction. Recruitment of muscles is to facilitate increased motor unit output for movement generation or strength. This is most commonly used when muscles have been weakened or inhibited as a result of injury, immobilization or surgical procedure of a limb/joint.

The majority of biofeedback research has focused on the effects of biofeedback therapy in the treatment of upper limb and lower limb motor deficits in neurological disorders (e.g., stroke). Traditionally biofeedback is presented to the patient and the clinician via visual displays, acoustic or vibrotactile feedback. A recent development in rehabilitation is exercising in a gaming or virtual reality (VR) environment, thus providing a novel form of immersive biofeedback. With VR the measured patient activity is fed back via graphical or audiovisual animations providing a realistic impression to the patient.

LITERATURE REVIEW

Urinary Incontinence

Pelvic floor muscle training is an established treatment option for urinary incontinence. Bladder training, changes in fluid intake, pharmacotherapy and surgical intervention may also be indicated based on the type of incontinence. Biofeedback is an established treatment modality for children and adults with stress, urge, mixed or overflow urinary incontinence that is unresponsive to other nonpharmacologic modalities such as bladder training and/or pelvic floor muscle training. Biofeedback may enhance awareness of body functions and assist the individual in learning muscle strengthening pelvic floor exercises There are several proposed methods of biofeedback which may be employed for the treatment of urinary incontinence including: vaginal cones, perineometers and electromyographic (EMG) systems (Holroyd-Leduc et al., 2008; Shamliyan et al., 2008; Payne, 2007). The published peer-reviewed scientific literature includes systematic reviews, randomized controlled trials, and case series that have reported an improvement in urinary incontinence for up to two years following biofeedback (Fitz et al., 2012; Herderschee et al., 2011; Desantis et al., 2011; Porena et al., 2000; Burgio et al., 2002; Herbison et al., 2002; Hunter et al., 2004; Yabci et al., 2005; Dannecker et al., 2005; Burgio et al., 2006; Klijn et al., 2006). In their guideline on the management of urinary incontinence in women, NICE (Sept 2015) stated that perineometry or pelvic floor electromyography as biofeedback should not be used as a routine part of pelvic floor muscle training, but biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy. In their guideline on the management of urinary incontinence in women, NICE (Sept 2015) stated that perineometry or pelvic floor electromyography as biofeedback should not be used as a routine part of pelvic floor muscle training, but biofeedback should be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy. The 2017 American Urological Society's (AUS) guidelines on the management of surgical treatment of female stress urinary incontinence (SUI) recommends that physicians counsel patients with stress urinary incontinence or stress-predominant mixed urinary incontinence who wish to undergo treatment. Counseling should include available treatment options including pelvic muscle floor training with or without biofeedback.

Hagen et al. (2020) assessed the effectiveness of pelvic floor muscle training (PFMT) plus electromyographic biofeedback or PFMT alone for stress or mixed urinary incontinence in women. Six hundred women aged 18 and older, newly presenting with stress or mixed urinary incontinence between February 2014 and July 2016 were included in the study: 300 were randomized to PFMT plus electromyographic biofeedback and 300 to PFMT alone. Participants in both groups were offered six appointments with a continence therapist over 16 weeks. Participants in the biofeedback PFMT group received supervised PFMT and a home PFMT program, incorporating electromyographic biofeedback during clinic appointments and at home. The PFMT group received supervised PFMT and a home PFMT program. PFMT programs were progressed over the appointments. The primary outcome was self-reported severity of urinary incontinence (International Consultation on Incontinence Questionnaire-urinary incontinence short form (ICIQ-UI SF), range 0 to 21, higher scores indicating greater severity) at 24 months. Secondary outcomes were cure or improvement, other pelvic floor symptoms, condition specific quality of life, women's perception of improvement, pelvic floor muscle function, uptake of other urinary incontinence treatment, PFMT self-efficacy, adherence, intervention costs, and quality adjusted life years. Authors report that at 24 months, no evidence was found of any important difference in severity of urinary incontinence between PFMT plus electromyographic biofeedback and PFMT alone groups. Routine use of electromyographic biofeedback with PFMT should not be recommended. Other ways of maximizing the effects of PFMT should be investigated.

Wu et al. (2021) compared the efficacy of PFMT with and without EMG-BF on the cure and improvement rate, PFM strength, urinary incontinence score, and quality of sexual life for the treatment of stress urinary incontinence (SUI) or pelvic floor dysfunction (PFD). The outcomes were the cure and improvement rate, symptom-related score, pelvic floor muscle strength change, and sexual life quality. Twenty-one studies (comprising 1967 patients with EMG-BF + PFMT and 1898 with PFMT) were included. Compared with PFMT, EMG-BF + PFMT had benefits regarding the cure and improvement rate in SUI and in PFD, and in quality of life. There was limited evidence of publication bias. PFMT combined with EMG-BF achieves better outcomes than PFMT alone in SUI or PFD management. Baumann et al. (2021) analyzed the specific exercise effects of supervised versus unsupervised pelvic floor muscle exercise (PFME) and exercise volume on urinary incontinence status after radical prostatectomy in a systematic review and meta-analysis. The meta-analysis included 20 randomized controlled trials involving 2188 men ($n = 1105$ in intervention groups; $n = 1083$ in control groups). PFME versus no PFME had a beneficial effect on urinary incontinence remission at 3 months, 3-6 months, and more than 6 months post-surgery, with risk differences ranging from 12 to 25%. These effects were particularly evident for higher volume, supervised PFME in the first 6 months post-surgery. Additional biofeedback therapy appeared to be beneficial but only during the first 3 months post-surgery. Authors concluded that there is good evidence that the supervised PFME causes a decrease in short-term urinary incontinence rates. Unsupervised PFME has similar effects as no PFME in postoperative urinary incontinence. PFME programs should be implemented as an early rehabilitative measure to improve postoperative short-term urinary incontinence in patients with prostate cancer.

Jacobsen et al. (2021) evaluated the efficacy of physiotherapeutic intervention with biofeedback assisted PFMT in children with DV. Children referred with DV, unresponsive to standard urotherapy were included in this study. All children underwent biofeedback assisted PFMT sessions with a physiotherapist. Uroflowmetries and measurements of post-void residual (PVR) urine were performed before and after the treatment, and the following parameters were registered; daytime incontinence (DI), nocturnal enuresis (NE), constipation, faecal incontinence (FI), and recurrent urinary tract infections (UTI). Other concomitant treatments were noted. The primary outcomes were the resolution of DV evaluated by uroflow curve configuration and PVR. Secondary outcomes were the resolution of DI, NE and the reduction of recurrent UTIs. Forty-six children (mean age 9.6 ± 2.4 years, 38 girls) were included in the analysis. The median period of treatment was 9.0 ± 8.5 months (2-9 visits). Twenty-seven (59%) children responded to treatment according to one or both primary outcomes; uroflow configuration (50%) and PVR (28%). DI resolved in 12 (26%) children and 27 of the 32 children, who prior to the treatment had recurrent UTIs experienced no UTIs during the follow up period. The use of anticholinergics was a significant negative predictor for response to treatment. Biofeedback assisted PFMT can improve the symptoms in children with DV. When comparing to existing literature they found a less pronounced effect of the intervention. A possible explanation may be that the children enrolled in this study were recruited from a tertiary referral centre and were all refractory to standard urotherapy. Moreover, the difference in patient characteristics and treatment protocols between different studies make direct comparisons of efficacy difficult. Authors concluded that physiotherapeutic intervention with biofeedback assisted PFMT seems to lead to better uroflow patterns in approximately 60% of cases in DV improving the uroflow curves and PVR, however improvement in uroflowmetry patterns is not necessarily reflected in the resolution of incontinence or UT symptoms. The use of anticholinergics seems to be a negative predictor for response to treatment.

Leonardo et al. (2022) compared biofeedback-assisted pelvic muscle floor training (PFMT) and pelvic electrical stimulation (ES) as an intervention group, with PFMT or bladder training (BT) as the control group, in women with an overactive bladder (OAB). Eight studies involving 562 patients (comprising 204 patients with biofeedback-assisted PFMT, 108 patients with pelvic ES, and 250 patients who received PFMT alone or BT and lifestyle recommendations only, as the control group) were included. The ES group showed significant differences in terms of changes to QoL, episodes of incontinence, and the number of participants cured or improved, while the biofeedback group resulted in nonsignificant changes in QoL, episodes of incontinence, and the number of participants cured or improved, both compared to the control group respectively. This meta-analysis shows that low-frequency pelvic ES appears to be sufficient and effective as an additional intervention for women with OAB in clinical practice according to improvements in the subjects' QoL and reduction of symptoms. Meanwhile, biofeedback-assisted PFMT does not appear to be a significant adjuvant for conservative OAB therapy.

Sam et al. (2022) compared the effectiveness of biofeedback-assisted pelvic floor muscle training (PFMT) and PFMT alone on voiding parameters in women with dysfunctional voiding (DV). The patients in group 1 (34 patients) were treated with biofeedback-assisted PFMT, and the patients in group 2 (34 patients) were treated with PFMT alone for 12 weeks. The 24-hour frequency, average voided volume, maximum urine flow rate (Qmax), average urine flow rate (Qave), post-void residual urine volume (PVR), and the validated Turkish Urogenital Distress Inventory (UDI-6) symptom scores were recorded before and after 12 weeks of treatment. At the end of treatment sessions, the Qmax and Qave values of the patients in group 1 were significantly higher than those in group 2, and the PVR in the patients in group 1 was significantly lower than those in group 2 (p=.026, .043, and .023, respectively). The average UDI-6 symptom scores of the patients in group 1 were significantly lower than those in group 2 (p=.034). Electromyography activity during voiding, in group 1 was significantly lower than in group 2 (41.2 vs. 64.7, respectively, p=.009). Authors concluded that biofeedback-assisted PFMT is more effective than PFMT alone in improving clinical symptoms, uroflowmetry parameters, and EMG activity during voiding.

Todhunter et al. (2022) summarised Cochrane Reviews that assessed the effects of conservative interventions for treating UI in women. Authors included reviews that compared a conservative intervention with 'control' (which included placebo, no treatment or usual care), another conservative intervention or another active, but non-conservative, intervention. Primary outcomes of interest were patient-reported cure or improvement and condition-specific quality of life. Twenty-nine relevant Cochrane Reviews were included. Seven focused on physical therapies; five on education, behavioural and lifestyle advice; one on mechanical devices; one on acupuncture and one on yoga. Fourteen focused on non-conservative interventions but had a comparison with a conservative intervention. There were 112 unique trials (including 8975 women) that had primary outcome data included in at least one analysis. Stress urinary incontinence (14 reviews): Conservative intervention versus control: there was moderate or high certainty evidence that pelvic floor muscle training (PFMT), PFMT plus biofeedback and cones were more beneficial than control for curing or improving UI. Urgency urinary incontinence (five reviews): Conservative intervention versus control: there was moderate to high-certainty evidence demonstrating that PFMT plus feedback, PFMT plus biofeedback, electrical stimulation and bladder training were more beneficial than control for curing or improving UI. Authors concluded that there is high certainty that PFMT is more beneficial than control for all types of UI for outcomes of cure or improvement and quality of life.

Fecal Incontinence

Biofeedback has been proposed for the treatment of fecal incontinence, and overall, results from systematic reviews and randomized controlled trials reported that biofeedback may help improve this condition in certain patients. However, studies primarily include small heterogeneous patient populations and diagnosis, short-term follow-up, and various biofeedback regimens and methods. Patient selection criteria with appropriate types of biofeedback regimens have not been established. In the guideline on the management of fecal incontinence, NICE (2007) stated that adults who have persistent fecal incontinence after initial management should be considered for special continence services including biofeedback. Due to the limited evidence, biofeedback is not recommended as a first line therapy. Brazzelli et al. (2011) conducted a systematic review of randomized and quasi-randomized controlled trials to assess the effectiveness of behavior and/or cognitive interventions, including biofeedback, for the treatment of children with fecal incontinence. Twenty-one trials (n=1371) met inclusion criteria. Follow-ups ranged from 4–24 months with two trials reporting no follow-up following cessation of treatment. Combined results of nine trials showed higher rates of persistent symptoms of fecal incontinence for up to 12 months when biofeedback was added to conventional treatment (e.g., laxatives, toilet training, dietary advice, behavior modification). Based on this data, the authors concluded that there was “no evidence” that biofeedback training added any benefit to conventional therapy for the management of functional fecal incontinence nor was there enough data to assess the effectiveness of biofeedback for the management of organic fecal incontinence in children. Norton and Cody (2012) conducted a systematic review of randomized and quasi-randomized controlled trial to evaluate biofeedback and/or anal sphincter exercises for the treatment of fecal incontinence in adults. Twenty-one studies (n=1525) met inclusion criteria. Two biofeedback studies reported follow-ups at nine months and five studies reported follow-ups at one year, but most studies reported no follow-up following cessation of treatment. The authors stated that they found no evidence that biofeedback provided any benefit over any other treatment (e.g., dietary modification, bulking agents, pelvic floor exercises) for fecal incontinence. Evidence on patient selection criteria is lacking. Overall, the limited number of studies with methodological weaknesses, including incomplete outcome data, did not allow for definitive assessment of the role of biofeedback in the treatment of adults with fecal incontinence.

Vonthein et al. (2013) conducted a systematic review of randomized controlled trials to evaluate the effectiveness of biofeedback (BF) and electrical stimulation (ES) for the treatment of fecal incontinence. Included studies evaluated BF, ES, BF plus ES, and/or pelvic floor exercises as a second-line therapy in adults who had no obvious need for surgery. The included studies also had to report patient-related outcomes (i.e., remission, response, and/or disease-related quality of life). Thirteen trials met inclusion criteria. In 12 trials, at least one study group received biofeedback typically in combination with ES or another modality. One study compared BF alone vs. ES alone and reported no significant differences in FI in either group following treatment. Two studies reported a significant improvement in the FI severity index, number of days with FI, anal squeeze and/or quality of life. However, the majority of studies reported no significant difference with the addition of biofeedback. The authors noted that BF seemed to be better than no BF and concluded that ES plus BF seemed to be the most effective treatment. Limitations of the studies investigating biofeedback for fecal incontinence included: small patient populations; heterogeneous populations (e.g., obstetrical trauma, elderly women); short-term follow-ups, conflicting outcomes, and missing data. The Italian Society of Colorectal Surgery (SICCR) and the Italian Association of Hospital Gastroenterologists (AIGO) joint committee developed a 2015 consensus statement for the treatment of fecal incontinence (FI). In the discussion of rehabilitative treatment for functional FI, the Committee reported that randomized controlled studies sustain the use of biofeedback. According to SICCR, a few studies suggested that adding biofeedback does not enhance the outcome of conservative management while other studies suggested that biofeedback and pelvic floor exercises be considered as a first-line option for patients who fail treatment with dietary changes, devices or drugs. Since there are no side effects, failure of biofeedback would not affect decisions regarding future therapy. Biofeedback with kinesitherapy (movement therapy) may also be a useful treatment. One study suggested biofeedback can be helpful after sphincteroplasty. The authors noted that techniques used for biofeedback and other modalities vary greatly and results of studies are not comparable (SICCR, 2015). Limitations of the studies evaluating biofeedback for the treatment of FI included: small, heterogeneous patient populations; heterogeneity of diagnosis, biofeedback methods and outcome measures; inconsistent statistically improved outcomes (e.g., embarrassment score, severity of FI, number of FI occurrences) across studies; lack of a control group; and conflicting outcomes. In some studies outcomes were not generalizable due to the diagnosis (e.g., obstetrical trauma).

The American Society of Colon and Rectal Surgeons (ASCRS) (2015) stated that biofeedback should be considered as an initial treatment of fecal incontinence in motivated patients with some preserved voluntary sphincter contraction. ASCRS noted that the benefits are variable and standard care (e.g., advice and education) alone have been shown to be as effective as biofeedback therapy. The recommendation is based on moderate-quality evidence and ASCRS noted that larger, well-designed studies are needed to make any definitive conclusions. In their 2015 guidelines for the efficacy of biofeedback for anorectal disorders, the American Neurogastroenterology and Motility Society (ANMS) and the European Society of Neurogastroenterology and Motility (ESNM) recommended biofeedback for the short- and long-term treatment of fecal incontinence for patients who have not responded to conservative medical treatment (e.g., antidiarrheals, fiber supplements). The guideline noted that treatment success is best defined as a 50% reduction in episodes of fecal incontinence, which has not been used in clinical trials. Other publications support this (Patcharatrakul and Rao, 2018; Rao et al., 2016). The Societies recommendation was based on nonrandomized studies rated as fair evidence and they noted that further research is needed to standardize the treatment protocols and the training of biofeedback therapists (Rao et al., 2015). Overall, studies investigating the effectiveness of biofeedback for fecal incontinence included small, heterogeneous patient populations and treatment regimens with short-term follow-ups. Biofeedback was used as an adjunctive therapy with various modalities. Outcomes were conflicting and several studies reported that no significant differences were seen with biofeedback. Because some studies included defined subpopulations (e.g., females with impaired fecal incontinence after obstetric anal sphincter injury) outcomes were not generalizable.

The Agency for Healthcare Research and Quality (AHRQ) conducted a 2016 comparative effectiveness review on treatments for fecal incontinence (FI) in adults. Thirteen randomized controlled trials examined pelvic floor muscle training (PFMT) and PFMT with biofeedback (PFMT-BF). Enrolled adults were mostly female with mixed FI etiologies. Meta-analysis was not possible due to the numerous outcomes that were used. PFMT-BF was the most frequently studied intervention. Outcomes included the frequency and severity of FI, quality of life and perceived improvement. AHRQ found that the evidence was insufficient to support PFMT-BF vs. standard care (e.g., dietary fiber, stool-modifying drugs, and/or advice). Low-strength evidence showed that PFMT-BF with electrostimulation was no more effective than PFMT-BF alone on FI severity and FI quality of life over two to three months. Although PFMT-BF showed improvement in FI outcomes, the improvements were not significantly different from the comparison groups. AHRQ noted that future studies should focus on longer term effects and attempt to identify subgroups of adults by FI etiology that might benefit from specific interventions.

Li et al. (2022) systematically reviewed and synthesized the evidence on the effectiveness of biofeedback therapy in patients with bowel dysfunction following rectal cancer surgery.

Randomized controlled trials (RCTs), cohort studies, and case series studies were included for adults with bowel dysfunction following rectal cancer surgery. All participants received an intervention of biofeedback treatment. Any outcomes that can evaluate the patient's bowel function were the primary research endpoint, while the quality of life was the second endpoint. Key findings included significant improvements in bowel function as well as health-related quality of life after biofeedback therapy. Authors concluded that although biofeedback therapy may improve intestinal function and quality of life as well as anal function after surgery, patient satisfaction is still unclear. Due to the scarcity of data, good-quality research is required to delve deeper.

Levator Ani Syndrome

In their 2015 guidelines for the efficacy of biofeedback for anorectal disorders, the American Neurogastroenterology and Motility Society (ANMS) and the European Society of Neurogastroenterology and Motility (ESNM) recommended biofeedback may be useful in the short-term treatment of Levator Ani Syndrome with dyssynergic defecation (Level II, Grade B) (Rao et al., 2015). Reports of biofeedback treatment for chronic functional anorectal pain have shown inconsistent results, and most of these were small and uncontrolled (46). However, a RCT of 157 well-characterized patients with LAS compared three treatments: biofeedback to teach pelvic floor muscle relaxation, electrogalvanic stimulation (EGS) to relax the pelvic floor, and digital massage of the levator muscles (Chiarioni et al., 2010). The primary outcome measure was the subjects' report of adequate pain relief. Key to the interpretation of the study was an a priori decision to test for tenderness when traction was applied to the levator ani muscles during digital rectal examination, and patients were stratified into the three treatment arms based on the presence or absence of tenderness. Among patients with tenderness on physical examination, adequate relief was reported by 87% with biofeedback, 45% with EGS and 22% with digital massage. However, none of these three treatments were effective in patients who did not report tenderness on physical examination (Chiarioni et al., 2010). The mixed results reported in previous biofeedback studies most likely were a consequence of failure to stratify patients based on the presence or absence of levator ani tenderness. Other publications also support this (Patcharatrakul and Rao, 2018; Rao et al., 2016). Biofeedback therapy has also been used to treat Solitary Rectal Ulcer Syndrome (SRUS) in open, short-term, small sized (less than 20 patients) studies. Inclusion criteria, physiological investigations and outcome parameters were variable. Biofeedback therapy was associated with symptom improvement in at least two thirds of patients with some histological improvement. Most notably, the highest successful outcome was reported when SRUS was associated with dyssynergic defecation (DD) (Rao et al., 2015). Narayanan et al. (2019) authored a review to update practitioners on recent advances and to identify practical obstacles to providing biofeedback therapy. Authors summarized recent findings: the efficacy and safety of biofeedback therapy evaluated in defecatory disorders, fecal incontinence, and levator ani syndrome. They note that based on literature, biofeedback therapy is effective for managing defecatory disorders, fecal incontinence, and levator ani syndrome. Biofeedback therapy is recommended for patients with fecal incontinence who do not respond to conservative management. A subset of patients with levator ani syndrome who have dyssynergic defecation are more likely to respond to biofeedback therapy.

Chronic Constipation

The evidence in the published peer-reviewed scientific literature supports the use of biofeedback for the treatment of constipation in adults. Significant improvements in constipation with biofeedback have been reported in systematic reviews, meta-analysis and randomized controlled trials (Skardoon et al., 2017; Woodward et al., 2014; Enck et al., 2009; Koh et al., 2008; Heyman et al., 2007; Rao et al., 2007; Chiarioni et al., 2006; Heyman et al., 2003). Biofeedback for the treatment of constipation in children is not well established and has not been proven to add additional benefit to established conventional therapy (Brazzelli et al. 2006; Brazzelli et al. 2004). The 2010 guideline (updated 2017) on the management of constipation in children and young adults by the National Institute for Health and Clinical Excellence (NICE) (United Kingdom) stated that biofeedback should not be used for ongoing treatment in children and young people with idiopathic constipation. Meta-analysis showed no improvement in outcomes when conventional treatment (e.g., use of laxatives, advice on a high-fiber diet, attempting defecation after meals) was compared to conventional treatment plus biofeedback. In a 2014 evidence-based guideline on the evaluation and treatment of functional constipation in infants and children, the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) concluded that the evidence did not support the use of behavioral therapy or biofeedback in the treatment of childhood constipation (Tabbers et al., 2014).

The 2013 American Gastroenterological Association's (AGA) position statement on constipation for adults stated that biofeedback improves symptoms in more than 70% of patients with defecatory disorders. Biofeedback can be used to train patients to relax their pelvic floor muscles during straining and to correlate relaxation and pushing to achieve defecation. The success of the therapy depends on the motivation of the patient and therapist, frequency and intensity of the retraining, and involvement of behavioral psychologist and dieticians. AGA "strongly recommends" "based on high quality evidence" that biofeedback be used rather than laxatives for defecatory disorders which are primarily characterized by impaired rectal evacuation from inadequate rectal propulsive forces and/or increased resistance to evacuation. In practice guidelines on the management of constipation, the American Society of Colon and Rectal Surgeons (ASCRS) (2016) states that in general, biofeedback should be used to treat slow-transit constipation and pelvic floor dyssynergia before subtotal colectomy. ASCRS recommended biofeedback as a first-line treatment option for patients with constipation due to symptomatic pelvic floor dyssynergia.

The American Neurogastroenterology and Motility Society (ANMS) and the European Society of Neurogastroenterology and Motility (ESNM) (Rao et al., 2015) provided evidence-based recommendations on the efficacy of biofeedback for anorectal disorders. The Societies conducted a review of the literature and used the U.S. Preventive Services Task Force evidence criteria to grade the recommendations. The Societies' recommendations included the following:

- Biofeedback is recommended for the short-term and long-term treatment of constipation with dyssynergic defecation (Level I, Grade A: evidence from at least one properly randomized controlled trial; good evidence; strongly recommends that clinicians routinely provide).
- Biofeedback may be useful for the short-term treatment of Levator Ani Syndrome with dyssynergic defecation (Level II, Grade B: nonrandomized studies; fair evidence; recommends that clinicians routinely provide) and solitary rectal ulcer syndrome with dyssynergic defecation (Level III, Grade C; opinions of authorities, based on clinical experience, descriptive studies and case reports or reports of expert committees; fair evidence; makes no recommendation).
- Biofeedback therapy is not recommended for the routine treatment of children with functional constipation, with or without overflow fecal incontinence. (Level I, Grade D; evidence from at least one properly randomized controlled trial; recommends against its use).

The French National Society of Coloproctology (Vitton et al., 2018) offers clinical practice recommendations for chronic constipation on the basis of the data in the current literature, including those on recently developed treatments. Most are noninvasive, and the main concepts include the following: stimulant laxatives are now considered safe drugs and can be more easily prescribed as a second-line treatment; biofeedback therapy remains the gold standard for the treatment of anorectal dyssynergia that is resistant to medical treatment. Moore and Young (2020) assessed the effectiveness of biofeedback therapy for dyssynergic defaecation using global clinical improvement as the primary outcome, and resolution of the dyssynergic pattern on anorectal physiology and quality of life as secondary outcomes in a systematic review and meta-analysis. Eleven trials including 725 participants were included in the narrative review. Sixty-three percent of patients treated with biofeedback reported clinical improvement. Six studies included in the meta-analysis showed biofeedback superior to non-biofeedback therapy for the primary outcome. Heterogeneity between trials and overall risk of bias was high. Authors concluded that biofeedback therapy is recommended for patients referred to tertiary units with dyssynergic defaecation who fail conservative therapy. In a paper on biofeedback for defecatory disorders, Hite and Curran (2021) state that biofeedback has demonstrated efficacy in the treatment of chronic constipation with dyssynergic defecation, fecal incontinence, and low anterior resection syndrome. Evidence for the use of biofeedback in levator ani syndrome is conflicting. In comparing biofeedback to pelvic floor muscle training alone, studies suggest that biofeedback is superior therapy.

Wegh et al. (2021) evaluated the effectiveness and safety of non-pharmacological interventions for the treatment of childhood functional constipation functional constipation. 52 RCTs were included with 4668 children, aged between 2 weeks and 18 years, of whom 47% were females. Studied interventions comprised of gut microbiome-directed interventions, other dietary interventions, oral supplements, pelvic floor-directed interventions, electrical stimulation, dry cupping, and massage therapy. An overall high risk of bias was found across the majority of studies. Meta-analyses for treatment success and/or defecation frequency, including 20 RCTs, showed abdominal electrical stimulation (n=3), Cassia Fistula emulsion (n=2), and a cow's milk exclusion diet (n=2 in a subpopulation with constipation as a possible manifestation of cow's milk allergy) may be effective. Evidence from RCTs not included in the meta-analyses, indicated that some prebiotic and fiber mixtures, Chinese herbal medicine (Xiao'er Biantong granules), and abdominal massage are promising therapies. In contrast, studies showed no benefit for the use of probiotics, synbiotics, an increase in water intake, dry cupping, or additional biofeedback or behavioral therapy. We found no RCTs on physical movement or acupuncture. Authors concluded that more well-designed high quality RCTs concerning non-pharmacological treatments for children with functional constipation are needed before changes in current guidelines are indicated.

Migraine and Tension-type Headache

Biofeedback is a standard treatment option for migraine and tension headaches. Systematic reviews and randomized controlled trials have reported that biofeedback is effective in reducing the severity and frequency of these headaches in adults and children (Vasudeva et al., 2003; Eccleston et al., 2004; Kaushik et al., 2005; Nestoriuc and Martin, 2007). After conducting a meta-analysis of 55 randomized controlled trials, including 1718 patients assigned to biofeedback and 511 patients assigned to controls, Nestoriuc and Martin (2007) stated that biofeedback could be recommended as an evidence-based behavioral treatment option for the prevention of migraine.

Neuromuscular Rehabilitation

There is sufficient evidence that EMG biofeedback is safe and effective for neuromuscular rehabilitation in patients who suffered from strokes (Giggins et al., 2013; Stanton et al., 2017). However, there is insufficient evidence that EMG biofeedback is effective as a rehabilitation modality for patients with spinal cord injury and in patients with spasmodic torticollis (Giggins et al., 2013). Additionally, although there is limited evidence that EMG biofeedback is effective in enhancing the return to full active knee extension and peak torque of the quadriceps femoris muscle following knee surgeries, there is little data on how these improvements translate clinically into improved functional outcomes (Giggins et al., 2013). For patients to potentially benefit from EMG biofeedback, they need to have some volitional muscle activity but remain disabled with no receptive aphasia. And biofeedback should be used when other standard forms of therapy have failed.

Pollock et al. (2003) conducted a systematic review on the recovery of postural control and lower limb function following stroke. The objective was to determine if outcomes were different if the physiotherapy treatment was based on orthopedic, neurophysiology, motor learning principles or a mixture of these modalities. The review included randomized or quasi-randomized controlled trials with interventions of physiotherapies, including biofeedback. Outcomes measured the degree of disability and motor impairment. Eighteen studies were categorized as EMG biofeedback and fifteen studies as positional biofeedback. The authors concluded that there was insufficient evidence to determine if one method was more effective than the other. Woodford and Price (2007) conducted a meta-analysis of 13 studies (n=269) on the use of electromyographic biofeedback (EMG-BFB) for the recovery of motor function following a stroke. The analysis included randomized controlled trials and quasi-randomized controlled trials that compared physiotherapy or exercises or physical therapy alone to these treatment modalities plus EMG/EMG-BFB. There were variations in the time from stroke to randomization (35 to 1140 days), and the length of the studies ranged from four to 16 weeks. Small sample sizes (n=10–40) were also a limitation of the studies. Outcome criteria included changes in motor strength, range of motion, stride length, gait speed, functional ability and gait quality score. Overall, the data did not demonstrate a positive effect on the outcomes. The authors concluded that EMG-BFB did “not appear to have a positive benefit for recovery after stroke,” and it could not be recommended as a routine treatment modality. Tate and Milner (2010) conducted a systematic review of randomized controlled trials (n=7) to evaluate the effectiveness of biofeedback in treating gait abnormalities. The types of biofeedback included real-time kinematic, temporospatial and kinetic. In five studies the patient population (n=105) was status-post stroke. One study included 42 patients with hip or knee replacement, hip fracture or amputation and one study included 28 patients’ status-post total hip replacement. There was a large range in the structure of the treatment protocol (e.g., treatment time, frequency, duration) and meta-analysis was not performed because of the wide variety of study designs, methodologies and outcome measures. Although some studies reported short-term improvement, long-term outcomes were not reported and whether or not improvements were maintained is unknown. The authors concluded that there was insufficient data to make a guideline recommendation for biofeedback for gait training.

Zijlistra et al. (2010) conducted a systematic review of randomized controlled trials (n=17) and comparative studies (n=4) to evaluate the effectiveness of biofeedback training for balance and/or mobility in older adults. Twelve studies included post-stroke patients, six included frail older adults in a care center and three studies included lower limb amputation and/or hip surgery. The biofeedback was visual and/or audio. The studies were determined to be of moderate quality with variations in analyses and outcomes. Due to the inability to perform quantitative analysis and the absence of large-scale randomized controlled trials, definitive conclusions could not be made. The addition of biofeedback during gait training did not seem to improve disability and mobility functioning. In their 2010 guidelines on stroke rehabilitation, the Department of Veterans Affairs, Department of Defense, American Heart Association and American Stroke Association recommended EMG biofeedback as a treatment modality for pain control when appropriate. However, "due to methodological flaws in current studies, further research is indicated to assess the efficacy of biofeedback as an adjunct to conventional therapy for post-stroke patients." Doğan-Aslan et al. (2012) evaluated the effect of electromyographic biofeedback (EMG-BF) treatment on wrist flexor muscle spasticity, upper extremity motor function, and ability to perform activities of daily living in patients with hemiplegia following stroke. A total of 40 patients were enrolled and were randomly assigned to two groups: a group treated with EMG-BF (study group) and an untreated (control) group. Both groups participated in a hemiplegia rehabilitation program consisting of neurodevelopmental and conventional methods. In addition, the study group received 3 weeks of EMG-BF treatment, 5 times a week, for 20 minutes per session at hemiplegic side wrist flexors. Clinical findings were assessed before and after rehabilitation using the Ashworth scale (AS), Brunnstrom's stage (BS) of recovery for hemiplegic arm and hand, the upper extremity function test (UEFT), the wrist and hand portion of the Fugl-Meyer scale (FMS), goniometric measurements of wrist extension, surface EMG potentials, and the Barthel Index (BI). There was no statistically significant difference between the two groups in terms of baseline measures. There also was no statistically significant difference in the pretreatment values between two groups. Authors noted statistically significant improvements posttreatment in the AS, BS, UEFT, goniometric measurements of wrist extension, and surface EMG potentials in the study group. They also noted statistically significant differences in the wrist and hand portion of the FMS and the BI in both groups, but with significantly greater improvements in the study group. Authors concluded that findings indicate a positive effect of EMG-BF treatment in conjunction with neurodevelopmental and conventional methods in hemiplegia rehabilitation.

Stanton et al. (2011) conducted a systematic review and meta-analysis of 22 randomized and quasi-randomized controlled trials to evaluate the effectiveness of biofeedback in enhancing lower-limb training for sitting, standing up, standing or walking following a stroke. Included clinical trials used various forms of biofeedback including any signal (position, EMG) via any sense (visual, auditor, tactile) during the practice of the whole activity. Based on pooled data from 17 trials (n=411) biofeedback improved lower limb activities compared to usual therapy or placebo in the short-term (i.e., one to five months following cessation of therapy). However, the authors noted that there was substantial heterogeneity of the low-quality trials using any form of biofeedback; lack of blinding of subjects and therapists; possible small trial bias and selection bias based on intervention in the studies used for meta-analysis; and only half of the trials measured outcomes for any length of time following cessation of therapy. Well-designed randomized controlled trials with long-term results are needed to support the effectiveness of biofeedback in stroke patients. Stanton et al. (2017) completed on systematic review with meta-analysis to determine if biofeedback during the practice of lower limb activities after stroke is more effective than usual therapy in improving those activities. Outcome measures were activity measures congruent with the activity trained. Eighteen trials including 429 participants met the inclusion criteria. The quality of the included trials was moderately high, with a mean PEDro score of 6.2 out of 10. Results demonstrated that biofeedback improved performance of activities more than usual therapy. Authors concluded that biofeedback is more effective than usual therapy in improving performance of activities. They also stated that further research is required to determine the long-term effect on learning and given that many biofeedback machines are relatively inexpensive, biofeedback could be utilized widely in clinical practice. Wattchow et al. (2018) investigated the therapeutic interventions reported in the research literature and synthesize their effectiveness in improving upper limb (UL) function in the first 4 weeks poststroke. A total of 104 trials (83 RCTs, 21 nonrandomized studies) were included (N=5225 participants). Evidence was found to support supplementary use of biofeedback and electrical stimulation. Authors concluded that use of modified constraint-induced movement therapy (mCIMT) and task-specific training was supported, as was supplementary use of biofeedback and electrical simulation, within the acute phase poststroke.

Lirio-Romero et al. (2021) examined the effects of a 6-week surface electromyographic biofeedback intervention on the re-learning of upper extremity motor function in subjects with paretic upper extremity after stroke. Thirty-eight participants in the sub-acute post-stroke stage were recruited and randomly allocated into either the surface electromyographic biofeedback (sEMG-BFB) or sham biofeedback (BFB) groups. The sEMG-BFB group (n=19) received the intervention focused on re-learning scapulothoracic control during arm-reaching tasks involving shoulder abduction. The sham BFB group (n=19) received a sham intervention. In the short term, a 6-week sEMG-BFB intervention effectively improved paretic upper limb motor function. Future research is needed to determine if the sEMG-BFB intervention has any long-term effects. Spencer et al. (2021) evaluated the state of the current evidence regarding the effectiveness of biofeedback for post-stroke gait training. Their overall goal was to determine whether gait biofeedback was effective at improving stroke gait deficits while also probing why and for whom gait biofeedback may be an efficacious treatment modality. Their literature review showed that the effects of gait biofeedback on post-stroke walking dysfunction are promising but are inconsistent in methodology and therefore results. There is a need for larger-sample studies that directly compare different feedback parameters, employ more uniform experimental designs, and evaluate characteristics of potential responders. However, as these uncertainties in existing literature are resolved, the application of gait biofeedback has potential to extend neurorehabilitation clinicians' cues to individuals with post-stroke gait deficits during ambulation in clinical, home, and community settings, thereby increasing the quantity and quality of skilled repetitions during task-oriented stepping training.

Balbinot et al. (2022) summarized the most common sEMG techniques used to address clinically relevant neurorehabilitation questions. Authors focused on the role of sEMG assessments in the clinical practice and research studies on neurorehabilitation after spinal cord injury (SCI), and how sEMG reflects the changes observed with rehabilitation. Of 4522 references captured in the primary database searches, 100 references were selected and included in the scoping review. The main focus of the studies was on neurorehabilitation using sEMG biofeedback, brain stimulation, locomotor training, neuromuscular electrical stimulation (NMES), paired-pulse stimulation, pharmacology, posture and balance training, spinal cord stimulation, upper limb training, vibration, and photobiomodulation. Authors concluded that most studies employed sEMG amplitude to understand the effects of neurorehabilitation on muscle activation during volitional efforts or reduction of spontaneous muscle activity (e.g., spasms, spasticity, and hypertonia). Further studies are needed to understand the long-term reliability of sEMG amplitude, to circumvent normalization issues, and to provide a deeper physiological background to the different sEMG analyses. This scoping review reveals the potential of sEMG in exploring promising neurorehabilitation strategies following SCI and discusses the barriers limiting its widespread use in the clinic.

Other Conditions

Biofeedback has been proposed as a treatment modality for numerous other conditions including: alcohol and drug abuse, anxiety disorders, asthma, autism spectrum disorders, cancer pain and symptoms, cardiovascular disease, cerebral palsy, acute and chronic back pain, chronic prostatitis, cystic fibrosis, epilepsy, fibromyalgia, functional dyspepsia, heart failure, hypertension, hyperhidrosis, knee osteoarthritis, labor pain, pervasive developmental disorders, posttraumatic stress disorder (PTSD), Raynaud's syndrome, recurrent urinary tract infection, reflex sympathetic dystrophy or complex regional pain syndrome, rheumatoid arthritis, spastic torticollis, temporomandibular disorders, tinnitus, type 2 diabetes mellitus, upper limb pain, vulvodynia and whiplash. However, the evidence in the published peer-reviewed scientific literature does not support the efficacy of biofeedback for the treatment of these conditions. Overall, there is a lack of randomized controlled trials using sufficient sample sizes, comparing biofeedback to established therapeutic modalities (e.g., pharmacotherapy, behavior therapy) with long-term follow-ups. Patient selection criteria for biofeedback for these conditions have not been established and reported sustained benefit past the treatment period are lacking (Hayes Inc., 2016; McKee and Moravec, 2010; Yilmaz, et al., 2010; Glasscoe and Quittner, 2008; McGinnis, et al., 2005).

Cancer: Patients undergoing oncologic therapy experience persistent pain, fatigue, anxiety and side effects from chemotherapy. In additional to pharmacotherapy, biofeedback has been proposed as an adjunct treatment modality for this patient population. However, there is insufficient evidence in the published peer-reviewed literature to support biofeedback for the management of cancer. There have been a limited number of studies with small patient populations (n=12-81), short-term follow-ups (e.g., 3 months) and in some studies, lack of a control group. Most studies were conducted prior to 2000. Biofeedback has not been shown to be effective in reducing cancer pain or chemotherapy side effects.

The American Cancer Society (2015) stated biofeedback under the supervision of a licensed biofeedback technician is a non-medical treatment that is sometimes used to help people relax and cope with pain and is typically used with other pain-relief methods. In their guideline on adult cancer pain (V.3.2019), the National Comprehensive Cancer Network (NCCN) recommends biofeedback as an option for psychological support (2A recommendation).

Chronic Neck, Upper Back and Low Back Pain: Biofeedback has been proposed as a treatment modality for chronic back pain to help relieve the tension in the back muscles and alleviate pain. Henschke et al. (2010) conducted a systematic review of 30 randomized controlled trials (RCTs) that investigated behavioral treatment (e.g., biofeedback) for low back pain. There was low quality evidence (three RCTs; n=64) that EMG biofeedback was more effective than waiting list or progressive relaxation (one RCT; n=24).

Ostelo et al. (2005) conducted a systematic review of the literature to determine if behavioral treatments (including biofeedback) for nonspecific chronic low back pain (CLBP) were more effective than other treatments compared to waiting-list controls (WLC). Twenty-one randomized controlled trials met inclusion criteria. CLBP was defined as back pain that persisted for 12 weeks or more. Studies of individuals with CLBP caused by pathological entities including infection, neoplasm, fracture, osteoporosis and rheumatoid arthritis (RA) were excluded. The investigators reported that there is moderate evidence (three studies, n=88) that there is no significant difference between EMG biofeedback and WLC on behavioral outcomes in the short term. There is conflicting evidence (two studies, n=60) on the effectiveness of EMG biofeedback versus WLC on general functional status. There is limited evidence (one study, n=28) of EMG biofeedback for a small short-term positive effect on back-specific functional status. Cognitive behavioral treatment (CBT) was compared to EMG biofeedback in one study (n=28), which found no differences in the groups for pain or any behavioral outcome measures either in the short or long term. A combination of CBT and EMG biofeedback compared to WLC (four studies, n=134) found strong evidence for a short-term, positive effect on pain intensity, but no differences on behavioral outcomes or general functional status in the short term compared to WLC. More research is needed to determine what types of behavioral interventions are most effective for pain relief and which patients would benefit most from a specific type of behavioral treatment. The investigators stated no determination could be made from this review as to whether patients should be referred to behavioral treatment programs or to active conservative treatment programs.

The American College of Physicians (ACP) (2017) developed guidelines based on an evidentiary review of the literature to provide clinical recommendations on noninvasive treatment of low back pain. ACP recommended that select nonpharmacologic treatment be used initially. Low quality evidence reported that electromyography biofeedback reduced pain compared to wait list but there was no effect on function.

The American Society of Anesthesiologist Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine (2010) stated that psychological treatment including biofeedback "may be used as part of a multimodal strategy for low back pain and for other chronic pain conditions".

Eslamian et al. (2020) sought to determine the differences between clinical effects of electroacupuncture and biofeedback therapy in addition to conventional treatment in patients with cervical myofascial pain syndrome (MPS). Fifty patients (N=50) aged 25-55 years of both sexes with chronic neck pain diagnosed with MPS (characterized by trigger points within taut bands) were randomly assigned to 2 equal groups of 25 individuals. The patients in electroacupuncture group were treated with standard acupuncture and concomitant electrical stimulation; those in biofeedback group received visual electromyography biofeedback therapy for muscle activity and relaxation. Both groups received the intervention 2 times a week for a total of 6 sessions. Basic exercise training and medicines were administered for all the patients. Authors concluded that both electroacupuncture and biofeedback therapies were found to be effective in management of MPS when integrated with conventional treatment. However, intergroup differences showed priority of acupuncture in some parameters vs biofeedback. Thus, electroacupuncture seems to be a better complementary modality for treatment of MPS in the neck and upper back area. Campo et al. (2021) evaluated the safety and efficacy of electromyographic and pressure biofeedback on pain, disability and work ability in adults with neck pain. Authors noted that moderate-quality evidence suggests biofeedback has a moderate effect on reducing short-term disability and a small effect on reducing intermediate-term disability. Biofeedback had no effect on pain or work ability in the short- and intermediate-term (low-to moderate-quality evidence). Authors conclude that biofeedback appears to have a small-to-moderate effect on reducing neck pain disability in the short- and intermediate-term, but no effect on pain or work ability. More trials reporting adverse events and comparing biofeedback to placebo are needed.

Wagner et al. (2021) evaluated evidence from the literature with a focus on the effect of biofeedback on pain reduction, overall symptom relief, physiological parameters and quality of life. Out of 651 studies, 37 quantitative studies of primary research evaluating pelvic pain conditions in male and female adults and children were included. They covered biofeedback interventions on anorectal disorders, chronic prostatitis, female chronic pelvic pain conditions, urologic phenotypes in children and adults and a single study on low back pain. For anorectal disorders, several landmark studies demonstrate the efficacy of biofeedback. For other subtypes of chronic pelvic pain conditions there is tentative evidence that biofeedback-assisted training has a positive effect on pain reduction, overall symptoms relief and quality of life. Authors conclude that for certain indications, biofeedback has been confirmed to be an effective treatment.

Epilepsy: In an effort to reduce abnormal brain waves and seizure frequency, biofeedback has been proposed for the treatment of epilepsy. Ramaratnam et al. (2008) conducted a meta-analysis of psychological treatments, including biofeedback, for epilepsy. Randomized and quasi-randomized studies were analyzed. Outcomes included quality of life and seizure frequency. Of the two trials including relaxation and behavioral therapy, one reported positive results by decreasing anxiety and enhancing adjustment. Another study of galvanic skin response reported reduction in seizure activity. A study using EEG biofeedback improved cognitive and motor functions in subjects with the greatest seizure reduction. The studies were deficient in methodology and due to the limited number of studies, the evidence wasn't considered reliable. In their clinical guideline for diagnosing and managing epilepsy in children and adults, NICE (2016) stated that psychological interventions, including biofeedback, may be used as an adjuvant therapy to anti-epileptic drugs (AED) to improve quality of life in adults who are not receiving optimal benefit from AED. However, psychological interventions have not proven to affect seizure frequency and are not an alternative to pharmacological treatment.

Fibromyalgia: Biofeedback has been proposed for the treatment of fibromyalgia in an effort to facilitate and train an individual in maintaining a state of relaxation and decreased pain. In a randomized controlled trial, Babu et al. (2007) compared EMG biofeedback (n=15) to sham (n=15) and reported a significant decrease in pain and the number of tender points in the treatment group. However, there were no significant differences in the fibromyalgia impact questionnaire, or the six-minute walk test. Both groups experienced a significant decrease in FIQ and visual analogue scale, but the decreases were greater in the biofeedback group.

Reneau (2020) reports that fibromyalgia (FM) is associated with debilitating pain and a reduced heart rate variability (HRV), reflecting decreased emotional adaptability and resistance to stress. Given this, they postulate that heart rate variability biofeedback (HRVB) may be effective in improving HRV, thus increasing stress resistance and emotional adaptability and reducing pain. They reviewed 22 articles and included six in this review. Five reported HRVB as a treatment for chronic pain, and one for FM pain. Overall, the articles in this review support the claim that HRVB is related to decreased pain. The researchers evaluated five HRVB programs, three on handheld devices and two on desktop computers. Authors conclude that despite the reviewed studies having methodological flaws, HRVB is a promising treatment for chronic pain. Larger, randomized controlled studies are needed to thoroughly evaluate the relationship between HRVB and FM pain.

Functional Dyspepsia (FD): Because low vagal tone may be a mediating mechanism by which psychological factors induce dyspepsia in FD, it has been hypothesized that biofeedback may be a helpful treatment modality by enhancing vagal tone, leading to improvement in parasympathetic activity and drinking capacity. In a randomized controlled trial (n=40), patients were allocated to investigation, information, and biofeedback with breathing exercises or to investigation and information only. Drinking capacity and quality of life significantly improved (p=0.02, p=0.01, respectively) following biofeedback, but an improvement in baseline vagal tone was not noted (Hjelland et al., 2007).

Hypertension: Because of its potential to decrease stress and enhance relaxation, biofeedback has been proposed for the treatment of hypertension. Greenhalgh et al. (2009) conducted a systematic review to determine the clinical benefits and long-term effects of biofeedback for the treatment of essential hypertension in adults. Forty-one studies, including 36 randomized controlled trials (n=1660), met inclusion criteria. Twenty-one trials used biofeedback only and 15 trials used biofeedback with other treatment modalities. No meta-analysis was completed due to the poor reporting quality of the studies and the large degree of heterogeneity of treatments and comparators. Overall, the trials included small patient populations, no follow-up or follow-up less than 12 months. Other limitations of the studies included the variation in interventions, inconsistencies in measurement of outcomes, and the conflicting and variable results. No consistent short- or long-term benefits in the control of hypertension were seen when biofeedback was compared to pharmacotherapy, sham biofeedback, no intervention or other behavioral therapies (e.g., relaxation, hypnosis, meditation, stress education).

Nakao et al. (2003) conducted a meta-analysis of 22 randomized controlled studies of essential hypertensive patients (n=905). Biofeedback intervention resulted in blood pressure reductions that were greater by 7.3 millimeters (mm) of mercury (Hg) systolic and 5.8 mmHg diastolic compared to nonintervention controls (such as clinical visits or self-monitoring of blood pressure). Compared to sham or nonspecific behavioral intervention controls, the net reductions in systolic and diastolic blood pressures by biofeedback intervention were 3.9 mmHg and 3.5 mmHg, respectively. Reviewers were unable to determine whether biofeedback itself had an antihypertensive effect beyond the general relaxation response because biofeedback was only found to be superior to sham or nonspecific behavioral intervention when combined with other relaxation techniques. The investigators concluded that large, randomized controlled trials are needed to determine whether biofeedback itself has an antihypertensive effect beyond the general relaxation response.

An evidence-based statement by the American Heart Association (AHA) included the investigation of biofeedback as an alternative therapy for lowering blood pressure (BP). AHA noted that the mechanisms responsible for BP lowering by biofeedback are incompletely described. Some evidence favors alteration in the autonomic nervous system balance. Systematic reviews and meta-analysis that have investigated biofeedback for this indication have reported conflicting results. Studies have been limited by "short duration, small sample sizes, difficulties with blinding, and significant heterogeneity when trial data were combined". Also, some meta-analyses have combined multiple complementary medicine techniques in their analyses, making it difficult to assess the impact of biofeedback alone. Due to the paucity of data, recommendation for using a specific biofeedback method could not be made. Overall, no significant adverse effects were reported. Based on this review, AHA stated that biofeedback may be considered in clinical practice to lower BP. This is a Class IIB, Level of Evidence B, recommendation meaning that the usefulness/efficacy of biofeedback is less well established and there is greater conflicting evidence from randomized controlled trials or meta-analysis (Brooke et al., 2013).

Elavally et al. (2020) investigated the effect of nurse-led home-based biofeedback intervention on the blood pressure levels among patients with hypertension. Uncomplicated primary hypertension outpatients were randomly assigned as study group (*n* = 173) and control group (*n* = 173) at a tertiary care hospital. Sociodemographic, clinical, and outcome variables [the baseline blood pressure and galvanic skin response (GSR)] were collected. Study group patients were given four teaching sessions of abdominal breathing-assisted relaxation facilitated by galvanic skin response (GSR) biofeedback. Daily home practice was encouraged and monitored to measure the effects on blood pressure and GSR at the end of the 1^{st}, 2^{nd}, and 3^{rd} month of intervention. The study group participants showed significant decrease in mean (SD) systolic and diastolic blood pressure. In contrast, control group participants had a mild increase in the mean systolic and diastolic blood pressure values from pretest to posttests. GSR showed a significant increase from 559.63 (226.33) to 615.03 (232.24), (F = 80.21) from pretest to posttest III. Authors concluded that use of home-based biofeedback-centered behavioral interventions enabled BP reduction among hypertensive patients. Further studies should use biochemical markers of sympathetic nervous system activity to endorse this home-based chronic illness intervention.

Burlaco et al. (2021) aimed to systematically review the literature to investigate the impact of HRV modulation through HRV-biofeedback on clinical outcomes in patients with CVD. Patients in the HRV-biofeedback group had significantly lower rates of all-cause readmissions than patients who received psychological education. Heart failure following HRV-biofeedback displayed an inverse association with stress and depression. HRV-biofeedback had beneficial effects on different cardiovascular diseases documented in clinical trials, such as arterial hypertension, heart failure, and coronary artery disease. Fournié et al. (2021) performed a review according to eligibility criteria including adult chronic patients, HRVB as main treatment with or without control conditions, and psychophysiological outcomes as dependent variables. In total, 29 articles were included. Reported results showed the feasibility of HRVB in chronic patients without adverse effects. Significant positive effects were found in various patient profiles on hypertension and cardiovascular prognosis, inflammatory state, asthma disorders, depression and anxiety, sleep disturbances, cognitive performance and pain, which could be associated with improved quality of life. Improvements in clinical outcomes co-occurred with improvements in heart rate variability, suggesting possible regulatory effect of HRVB on autonomic function. Authors concluded that HRVB could be effective in managing patients with chronic diseases.

Irritable Bowel Syndrome (IBS): The clinical guideline on the management of irritable bowel syndrome (IBS) published by NICE (2008; updated 2017) stated that reviews of biofeedback suggested a positive effect on the control of IBS symptoms, but evidence was limited and not sufficient to make recommendations. A systematic review of the literature identified four randomized controlled trials that met inclusion criteria. One study compared biofeedback to counseling and three studies evaluated multi-component therapy (a combination of educational information, progressive relaxation therapy, thermal biofeedback treatment and training in stress coping strategies) compared to symptom monitoring or attention placebo controls. There was limited, weak evidence to show a statistically significant improvement in global symptoms for biofeedback and reduction in diarrhea compared to symptom monitoring. No significant differences between biofeedback and attention placebo or between symptom monitoring and attention placebo were reported, but there was much uncertainty due to wide confidence intervals. There was insufficient evidence to determine the effects of biofeedback on pain, bloating and constipation. A Cochrane Review by Goldenberg et al. (2019) also concluded that there is currently not enough evidence to assess whether biofeedback interventions are effective for controlling symptoms of IBS.

Labor Pain: In a systematic review, Jones, et al. (2012) summarized the evidence on the efficacy and safety of non-pharmacological and pharmacological interventions to manage labor pain. Fifteen Cochrane reviews (*n*=255 trials) and three non-Cochrane reviews (*n*=55 trials) met inclusion criteria. There was insufficient evidence from four randomized controlled trials (*n*=201) to determine if biofeedback was more effective than placebo or other interventions for labor pain management.

Barragán et al. (2011) conducted a systematic review of randomized controlled trials to evaluate the efficacy of biofeedback in the management of labor pain. Four trials (*n*=186) met inclusion criteria and primarily used EMG biofeedback. There were no significant differences between biofeedback and the control groups in terms of assisted vaginal birth, caesarean section, augmentation of labor and the use of pharmacological pain relief. Some studies reported that EMG biofeedback may have had some positive effects early in labor, but as labor progressed there was a need for additional pharmacological analgesia.

Knee Conditions: Richard et al. (2017) conducted a systematic review of the literature to evaluate the effectiveness of real-time biofeedback as a method for gait retraining to reduce knee adduction movement (KAM) in patients with knee osteoarthritis (KOA). Twelve uncontrolled studies met inclusion criteria. Seven studies used healthy subjects and five studies enrolled patients with KOA. Because of the lack of studies reporting between-group effects, this review focused on within-group effects. Within-group standardized mean differences (SMDs) for reduction of KAM in healthy controls ranged from 0.44 to 2.47 and from 0.29 to 0.37 in patients with KOA. In patients with KOA, improvements were reported in pain and function, with SMDs ranging from 0.55 to 1.16. Limitations of the studies included: small number of studies that enrolled KOA patients; small patient populations; heterogeneity of study design, methods of feedback and number of training sessions (many studies only reported on one session); short-term follow-ups (e.g., one month); and lack of a comparator and control group. The authors noted that there was insufficient information to conclude the optimal method of feedback delivery or the optimal instructions for subjects to achieve KAM reductions. Additional studies with large patient populations and long-term follow-up are needed to support biofeedback for this indication.

Wasielewski et al. (2011) conducted a systematic review of eight randomized controlled trials (n=319 subjects) to evaluate the effectiveness of electromyographic biofeedback (EMGB) of the quadriceps femoris muscle for the treatment of knee conditions. Diagnosis included patellofemoral pain syndrome (two trials; n=86), anterior cruciate ligament reconstruction (two trials; n=52), arthroscopic surgery (two trials; n=91) or osteoarthritis (two trials; n=90). EMGB appeared to benefit short-term postsurgical pain or quadriceps strength in three out of the four postsurgical investigations but was reported ineffective for chronic knee conditions including patellofemoral pain and osteoarthritis. Limitations of the studies included small heterogeneous patient populations, variability in interventions and outcomes, and poor methodology. The authors stated that the results should be viewed with caution due to the limited data and poor studies.

Karaborklu Argut et al. (2021) presented an evidence-based overview of the current utilization and the effectiveness of therapeutic Electromyographic Biofeedback (EMG-BF) in rehabilitation after orthopedic knee surgeries. Eight RCTs investigating effectiveness of the EMG-BF in rehabilitation after orthopedic knee surgeries were identified. Most of the included studies reported that EMG-BF was more effective compared to home exercises, standard rehabilitation program or electrical stimulation for improving quadriceps strength or activation. Besides, EMG-BF was revealed positive results in functional assessments except gait velocity and IKDC. Only two studies reported knee ROMs were significantly improved in favor of EMG-BF. Authors concluded that EMG-BF seems to control pain and improve quadriceps femoris strength and functionality. However, the results are inconclusive regarding knee ROM. Although available high-quality evidence is limited, EMG-BF might be a part of the rehabilitation after knee surgeries.

Xie et al. (2021) aimed to determine whether EMG-biofeedback is effective for improving the range of motion (ROM), physical function, and pain relief in patients after knee surgery.

Randomized controlled trials (RCTs) assessing the effect of EMG-biofeedback after any knee surgery were retrieved. This review identified 773 unique studies, and six RCTs were in the final meta-analysis. EMG-Biofeedback treatment has a significant difference compared to other rehabilitation therapy in knee ROM improving). Moreover, there was no significant difference in pain and physical function. The results illustrate that EMG-biofeedback can improve knee ROM in patients after knee surgery. However, it is not superior to other rehabilitation methods for pain relief and physical function improvement.

Glattke et al. (2022) completed a systematic review on rehabilitation after ACL reconstructive surgery. A total of 824 articles from 2012 to 2020 were identified using multiple search engines. Fifty Level-I or II studies met inclusion criteria. Authors stated that electromyography biofeedback may help to regain muscular function.

Nonneuropathic Voiding Disorders: Fazeli et al. (2014) conducted a systematic review and meta-analysis to evaluate biofeedback for the treatment of nonneuropathic daytime voiding disorders (NVD) in children. The hallmark of nonneuropathic voiding disorders is lower urinary tract symptoms with or without urinary incontinence. Five randomized controlled trials (*n*=487) met inclusion criteria and four studies (*n*=382) were included in the meta-analysis. At six months follow-up, there were no significant differences in the number of cases with resolved incontinence, mean maximum urinary flow rate or the likelihood of urinary tract infection with biofeedback vs. control group without biofeedback. The data does not support biofeedback for the treatment of this subpopulation.

Qi et al. (2022) assessed the efficacy of biofeedback treatment for children's non-neurogenic voiding dysfunction (NVD), which is a syndrome characterized by lower urinary tract symptoms (LUTs) because of the inability to relax the external sphincter. Patients with NVD always suffer from urinary tract infections (UTI), incontinence, constipation. Fifteen studies and 1274 patients were included in the systemic review, seven RCTs and 539 patients were included in meta-analysis. Meta-analysis showed efficacy of biofeedback treatment in following aspects, (1) relieving UTI, (2) reducing PVR, (3) increasing maximum urine flow rate and average urine flow rate, (4) relieving constipation, (5) improving abnormal voiding pattern and abnormal EMG during voiding. The improvement of UTI symptoms, maximum urine flow rate and average urine flow rate took a longer time (12 months). In terms of daytime incontinence, nighttime incontinence, no significant difference was found between biofeedback treatment and standard urotherapy. The qualitative analysis showed that biofeedback treatment was beneficial for NVD. Authors concluded that compared with standard urotherapy, biofeedback treatment is effective for some symptoms, such as UTI and constipation, and can improve some uroflowmetric parameters, such as PVR. Biofeedback treatment seems to have a better long-term effect.

Raynaud's Syndrome: Proponents of biofeedback for Raynaud's state that using thermal biofeedback to produce vasodilation may help relieve the severity and frequency of attacks. Malenfant et al. (2009) conducted a systematic review and meta-analysis of randomized controlled trials on complementary and alternative medicine, including biofeedback (n=5 studies), for the treatment of Raynaud's phenomenon. The outcomes of the biofeedback studies (n=15–155) favored sham therapy over biofeedback ($p<0.02$). There were no significant differences in frequency or duration or severity of Raynaud's attacks. The authors concluded that biofeedback is not an effective therapeutic intervention for the treatment of Raynaud's.

Recurrent Urinary Tract Infection: Minardi et al. (2010) conducted a randomized controlled trial to evaluate the efficacy of uroflowmetry biofeedback and pelvic floor relaxation biofeedback in women (n=86) with more than a three-year history of recurrent urinary tract infections (UTI) (i.e., three or more symptomatic episodes per year) and dysfunctional voiding. The authors defined dysfunctional voiding as an abnormally learned spectrum of voiding behavior in neurologically normal individuals. The women were randomized to one of four groups: group 1 (n=24), uroflowmetry biofeedback; group 2 (n=21), biofeedback training of the pelvic floor muscles; group 3 uroflowmetry biofeedback combined with biofeedback training of the pelvic floor muscles; and group 4 no treatment. Patients also received antibiotics during the study when indicated. At the three-, six- and 12-month follow-ups there were significant improvements ($p<0.05$, each), which remained stable, in all of the following outcome measures: storage and emptying symptoms, mean flow rate, flow time, voiding and volume; overall voiding pattern; post-void residual urine; mean opening detrusor pressure and detrusor pressure at maximum flow; and the prevalence of UTI. No significant improvements were seen in the untreated group. At 24 months in the treated groups, the storage and emptying symptoms and voiding patterns were similar to baseline values in 55% of patients, and the incidence of UTIs was similar in 45% of patients. The authors noted that this was the first study of pelvic floor therapy for the treatment of recurrent UTIs in women. Limitations of the study include the small patient population, short-term follow-up and the number of patients lost to follow-up (142 were originally enrolled).

Rheumatoid Arthritis (RA): Biofeedback has been proposed for the treatment of RA to help alleviate tension, stress, anxiety, insomnia and other symptoms that may cause acute flair-ups and/or enhance arthritic pain. Astin et al. (2002) conducted a systematic review of the literature to investigate the effect of psychological interventions (including biofeedback) on patients with RA. Outcome measures included functional ability, pain, tender joints, psychological status and coping ability. Twenty-five randomized controlled trials (n=1676) met inclusion criteria. Because separate results by type of intervention (i.e., relaxation, biofeedback, CBT) were not identified, the authors could not report which psychological interventions or combinations of interventions were most effective and for which types of patients. Methodological flaws in the studies included: inadequate description of controls and the effect sizes were not always consistent with signs of confidence intervals. The authors concluded that more research was needed to determine which treatments may be of benefit for patients with RA.

Sleep Bruxism: Biofeedback has been proposed as a treatment option for sleep bruxism, a sleep-related disorder characterized by teeth grinding or jaw clenching. In a systematic review of seven randomized controlled trials (*n*=240), Wang et al. (2014) concluded that the evidence did not support biofeedback for this condition. Meta-analysis showed no significant differences between biofeedback and controls (p=0.26). The studies were limited by the heterogeneity of the biofeedback modalities (i.e., auditory, electrical and visual feedback) and regimens, and the use of various control modalities (e.g., splint, occlusal adjustment) and outcome measures. The classification of risk of bias was moderate to high. Jokubauskas and Baltrušaitytė (2018) updated the review published by Wang et al in 2014. The review focuses on the most recent literature on management of sleep bruxism (SB) with biofeedback. Six articles of 2320 identified citations involving 86 adult participants were included in the qualitative synthesis. Of them, 4 were randomized controlled trials (RCTs) and 2 were uncontrolled before-after studies. Different feedback modalities (electrical, auditory and vibratory stimulus) were investigated. The meta-analysis indicated a non-significant difference in electromyographic-measured SB episodes per hour after one night of contingent electrical stimulation (CES) compared with placebo control, yet a significant difference was shown after five nights of CES. The quality of evidence was graded from low to moderate, due to imprecision and inconsistency between studies. Authors concluded that one of the biofeedback modalities, CES, is effective in reducing SB-related motor activities after a short-term treatment period. However, evidence of long-term effects is lacking. Further longitudinal studies with larger samples are necessary to acknowledge the clinical application of biofeedback. Bussadori et al. (2020) mapped the evidence from systematic reviews (SR), examining the effects of interventions to improve chronic pain related to bruxism. There was no difference in pain and bruxism frequency between biofeedback therapy and an inactive control group. Authors concluded that there was no evidence was provided to support the recommendation of biofeedback therapy and drug therapy. There is still a need for more methodologically rigorous randomized clinical trials (RCT) to be conducted on the efficacy and safety of different therapies for SB.

Temporomandibular Disorders (TMD)/Temporomandibular Joint (TMJ) Disorders: As in other chronic pain conditions, biofeedback has been investigated to determine if relaxation and relief of stress and tension following biofeedback would alleviate the pain of TMD. A systematic review by Medlicott and Harris (2006) included seven randomized controlled trials which evaluated the effectiveness of relaxation training or biofeedback in the management of TMD. From the review of these studies, the authors stated that programs involving relaxation techniques and biofeedback, EMG training, and proprioceptive reeducation may be more effective than placebo or occlusal splints in decreasing pain and increasing total vertical opening in patients with acute or chronic myofascial or muscular TMD. However, it was noted by the authors that "these recommendations should be viewed cautiously."

In a 2005 systematic review, Crider et al. reported on six randomized controlled trials regarding the efficacy of biofeedback-based therapy for TMD. Two trials included surface electromyographic (SEMG) training of masticatory muscles; two combined SEMG with cognitive-behavioral therapy (CBT); and two involved biofeedback-assisted relaxation training (BART). The review determined the extent that each intervention met treatment efficacy criteria established by the Association for Applied Psychophysiology and Biofeedback (AAPB). Based upon the review of the studies, the authors stated that SEMG training and BART were "probably an efficacious treatment" and SEMG with CBT is an efficacious treatment. They recommended additional studies to identify specific treatment combinations.

Tinnitus: Weise et al. (2008) conducted a randomized controlled trial to compare the effects of biofeedback (*n*=63) to a wait-list control group (WLG) (*n*=67) in patients with chronic tinnitus (i.e., more than six months duration). Patients underwent 12, one-hour EMG biofeedback sessions with tinnitus-specific cognitive– behavioral therapy (CBT) (e.g., directing attention away from tinnitus, relapse prevention) over a three-month period. Final follow-up occurred six months following cessation of treatment. Following treatment, intention-to-treat statistical analysis based on results of interviews and self-reported questionnaires showed significantly less emotional and cognitive distress; less intrusive tinnitus, less auditory perceptual difficulties, less sleep disturbances and fewer somatic complaints in the biofeedback group ($p<0.01$ for each). No significant differences were reported in the WLG. Compared to pretreatment and the WLG, patients in the biofeedback group reported fewer feelings of helplessness, increased feelings of resourcefulness, fewer catastrophizing self-statements, and more helpful coping self-statements. However, no significant effect was found for depressive and general psychopathological symptoms. Following a waiting period, 52 WLG patients received biofeedback and showed a significant improvement in outcomes. The authors noted that the study was limited by the WLG instead of an active treatment control group (CBT without biofeedback). Other limitations of the study are the short-term follow-up, and the dropout rate (*n*=26).

Upper Limb Pain: A limited number of studies have been conducted to determine if the muscle relaxation effect of biofeedback could help alleviate the pain of repetitive strain in the upper limbs. Karjalainen et al. (2004) conducted a systematic review of the literature to determine the effectiveness of biopsychosocial rehabilitation for upper-limb repetitive strain injuries among working-age adults. Two prospective randomized studies (*n*=80) met inclusion criteria and both were considered to be of low quality due to methodological flaws. Studies which included EMG biofeedback as the only component of physiological rehabilitation were excluded. The authors concluded that there were no differences in effect between applied relaxation, EMG biofeedback plus applied relaxation, and waiting-list controls after eight weeks and six months of follow-up.

Vulvodynia: Following the hypothesis that vulvodynia, also called vulvar vestibulitis or vulvar vestibulodynia, may be due to an abnormality in pelvic floor muscle tone, biofeedback has been investigated as a treatment modality for muscle training. In a randomized controlled study, Bergeron et al. (2001) prospectively evaluated and compared EMG biofeedback (12-week trial), group cognitive-behavioral (12-week trial), and vestibulectomy in the treatment of dyspareunia resulting from vulvar vestibulodynia. Seventy-eight women were randomly assigned to one of the three treatment regimens. Following treatment, all groups reported statistically significant reductions on pain measures up to the six-month follow-up. The vestibulectomy group was significantly more successful than the other two groups, reporting a 70% mean reduction in pain and a greater quality of life improvement. The biofeedback participants experienced a higher six-month dropout rate, reflecting patient difficulty following through with the long-term and repetitive treatment protocols. The authors stated that the results should be interpreted with caution because there were significantly more participants in the vestibulectomy condition who refused to undergo the treatment they had been randomized to, as compared to participants in the two other treatment conditions".

The American Society for Colposcopy and Cervical Pathology's (ASCCP) vulvodynia guideline update (Stockdale, et al., 2013) stated that biofeedback may be used in the treatment of vulvodynia to aid patients in confronting and reducing pain.

In a 2016 updated Committee Opinion on persistent vulvar pain, the American Congress of Obstetricians and Gynecologists (ACOG) and American Society for Colposcopy and Cervical Pathology (ASCCP) recommendations and conclusions stated that women with vulvodynia should be assessed for pelvic floor dysfunction. Biofeedback and/or physical therapy, including pelvic floor physical therapy can be used to treat localized and generalized vulvar pain especially if there is concomitant vaginismus.

<u>EEG Biofeedback/Neurofeedback</u>

The evidence in the clinical trials has not established clinical efficacy and effectiveness of EEG biofeedback for any indication. Studies include small patient populations and heterogeneous types of neurofeedback with short-term follow-ups (Lee et al., 2015; Angelakis, et al., 2007; Dohrmann, et al., 2007; McDonough-Means and Cohen, 2007).

Renton et al. (2017) conducted a systematic review to evaluate the effectiveness of neurofeedback (NF) as a form of cognitive rehabilitation therapy for the treatment of stroke patients. Studies included subjects who were affected by a cognitive deficit following stroke (e.g., memory loss, loss of executive function, speech impairment). Seven studies met inclusion criteria including one randomized controlled trial, one non-randomized comparative trial, one case series and four case reports. Study designs and NF therapy and training protocols were heterogeneous. NF protocols were highly specific to each study (i.e., feedback location, number of sessions, training task involved, etc.). The majority of patients demonstrated moderate cognitive improvements in their respective pre-post NF outcome measures including reported improvements in memory, mood, concentration, energy, reading and speech abilities, and/or motivation. The authors noted that it was unlikely that NF alone was responsible for the improved results. Because of the heterogeneity of the studies, meta-analysis could not be performed. Limitations of the studies include heterogeneous types of NF therapy; small patient populations; lack of a comparator; heterogeneity of the study designs; and poor quality of the studies. There is insufficient evidence to support NF therapy for cognitive rehabilitation of stroke patients.

Reiter et al. (2016) conducted a systematic review of the literature to assess the effectiveness of neurofeedback (NF) for the treatment of posttraumatic stress disorder (PTSD). Five studies including one randomized controlled trial met inclusion criteria. Three studies used neurofeedback for combat-related PTSD. One study focused on children with insecure attachment and trauma-related PTSD and one study included participants with PTSD related to childhood abuse. NF approach included alpha wave, alpha/theta training, sensorimotor rhythm, or combination NF. Training sessions varied from 30 minutes to one hour and ranged from one single session to 30 sessions. Three studies reported a statistically significant reduction in targeted symptomatology while some measures failed to show any improvement. Limitations of the studies include limited number of studies; small patient populations (10–29); lack of female subjects; short-term follow-ups; lack of a comparator, and heterogeneity of treatment protocol and outcomes. Data are insufficient to support neurofeedback as an effective treatment option for PTSD. Additional research using well-designed randomized controlled trials with large patient populations is needed to establish which neurofeedback approach is clinically effective for PTSD.

Luctkar-Flude et al. (2015) conducted a systematic review of the literature to evaluate the safety and effectiveness of neurofeedback of the management of fatigue and cognitive impairment. Seven randomized, three quasi-randomized and four nonrandomized trials (case series and retrospective reviews) met inclusion criteria. A study was eligible for inclusion if it included adult cancer survivors, individuals with other chronic health conditions or nonclinical populations seeking to decrease fatigue and/or enhance cognitive abilities. Two studies included cancer patients. Most of these studies reported positive results for at least one fatigue or cognitive outcome in a variety of clinical populations (traumatic brain injury, fibromyalgia, CNS problems) and nonclinical (college students, adults, elderly). Limitations of the studies included: small patient populations; heterogeneity of the types of neurofeedback, comparators, number of training sessions, outcome measures and diagnosis; subjects lost to follow-up; and short-term follow-ups Only four studies reported side effects or safety issues. Due to the limitations of the studies firm conclusions could not be made regarding the effectiveness of neurofeedback for fatigue and cognitive impairment including cancer patients.

A Hayes (2003) review of six studies that met inclusion criteria concluded that “there is insufficient evidence from the available peer-reviewed literature to conclude that EEG biofeedback therapy is effective for the treatment of disorders such as epilepsy, insomnia, depression, mood disorders, posttraumatic stress disorder, alcoholism, drug addiction, or menopausal symptoms”. Limitations of the studies included small patient populations, inadequate or no controls, lack of randomization or comparison to conventional therapies, and/or long-term follow-up, as well as inconsistent outcome measures and incomplete reporting of data. Because of these methodological flaws, Hayes stated that “no definitive conclusions regarding the efficacy of EEG biofeedback can be drawn.” In a subsequent literature search (2008), Hayes’ conclusions had not changed. This report has been archived.

The American Academy of Pediatrics (AAP) Task Force on Mental Health (2010) published a mental health tool kit for primary care clinicians as a guide for mental health care for pediatric practices. Included in the supplement is an “Evidence Based Child and Adolescents Psychosocial Interventions” document developed by using data from the PracticeWise Evidence-Based Services Database. The table lists primary problem areas and interventions based on the level of support. Biofeedback is listed as a level 4, minimal support, for anxious or avoidant behaviors and a level 5, no support for autism spectrum disorders. According to the authors the ratings are based on an ongoing review of randomized clinical psychosocial and combined treatment trials for children and adolescents with mental health needs.

Patel et al. (2020) evaluated the effectiveness and safety of neurofeedback (NFB) in alleviating pain and pain-associated symptoms in chronic pain patients. Twenty-one studies were included. Reduction in pain following NFB was reported by one high-quality RCT, five of six low-quality RCT or NRCT and 13 of 14 case-series. Pain reduction reported by studies ranged from 6% to 82%, with 10 studies reporting a clinically significant reduction in pain of >30%. The overall effect size was medium (cohen’s d - 0.76). Studies were highly heterogeneous. Improvements in depression, anxiety, fatigue and sleep were also seen in some studies. Common side-effects included headache, nausea and drowsiness. Authors concluded that neurofeedback is a safe and effective therapy with promising but largely low-quality evidence supporting its use in chronic pain. Further high-quality trials comparing different protocols is warranted to determine the most efficacious way to deliver NFB.

Steingrimsson et al. (2020) aimed to assess whether EEG-NF, compared with sham NF, other treatment, or no treatment, is effective for PTSD. Primary outcomes were self-harm, PTSD symptoms, level of functioning and health-related quality of life. Four RCTs were included (123 participants). Suicidal thoughts were significantly reduced after EEG-NF compared with a waiting list in a small study. PTSD symptoms were assessed in all studies with different instruments. Results were consistently in favor of EEG-NF with large effect sizes. One study reported significantly improved level of executive functioning and one study a reduction in use of psychotropic medication. Complications were scarcely reported. Certainty of evidence was assessed as very low for the four assessed outcomes. Authors concluded that based on four RCTs, with several study limitations and imprecision, it is uncertain whether EEG-NF reduces suicidal thoughts, PTSD symptoms, medication use, or improves function. Although all studies showed promising results, further studies are needed to increase the certainty of evidence.

Hesam-Shariati et al. (2022) synthesized the evidence from randomized controlled trials (RCTs) to evaluate the effect of EEG neurofeedback on chronic pain using random effects meta-analyses. Additionally, they performed a narrative review to explore the results of non-randomized studies. Ten RCTs and 13 non-randomized studies were included. The primary meta-analysis on nine eligible RCTs indicated that although there is low confidence, EEG neurofeedback may have a clinically meaningful effect on pain intensity in short-term. Removing the studies with high risk of bias from the primary meta-analysis resulted in moderate confidence that there remained a clinically meaningful effect on pain intensity. Authors concluded that although there is promising evidence on the analgesic effect of EEG neurofeedback, further studies with larger sample sizes and higher quality of evidence are required.

Fernández-Alvarez et al. (2022) conducted a meta-analysis of studies extracted from PubMed, Scopus, Web of Science and Embase with two objectives: A first group comprising studies patients with major depressive disorder (MDD) and a second group including studies targeting depressive symptomatology reduction in other mental or medical conditions. In the first group of studies including patients with MDD, moderator analyses indicate that treatment efficacy is only significant when accounting for experimental design, in favor of randomized controlled trials (RCTs) in comparison to non RCTs, whereas the type of neurofeedback, trial design, year of publication, number of sessions, age, sex and quality of study did not influence treatment efficacy. In the second group of studies, a small but significant effect between groups was found in favor of bio- and neurofeedback against control groups. Moderator analyses revealed that treatment efficacy was not moderated by any of the sociodemographic and clinical variables. Authors concluded that heart rate variability (HRV) biofeedback and neurofeedback are associated with a reduction in self-reported depression. Despite the fact that the field has still a large room for improvement in terms of research quality, the results presented in this study suggests that both modalities may become relevant complementary strategies for the treatment of MDD and depressive symptomatology in the coming years.

Lima et al. (2022) reviewed the studies that investigated the effects of EEG neurofeedback in subjects with alcohol use disorder (AUD) and it proposes to discuss this intervention as a tool for reducing harm and risk in AUD. Most of the papers analysed used the alpha/theta protocol to reduce the 'hyperexcitation' of the nervous system. This protocol provides relaxation, decreases anxiety or stress, prevents alcohol relapse, maintains abstinence and increases the feeling of well-being. EEG neurofeedback has important effects on AUD and anxiety or stress. Studies reinforce the use of EEG neurofeedback as an alternative tool for reducing harm and risk in AUD. EEG neurofeedback is an intervention to treat AUD, specifically, to reduce harm and risk. However, more randomised studies are necessary to consolidate and confirm the effectiveness of the technique despite these findings.

Pindi et al. (2022) provide 1) a state-of-art qualitative review of real-time functional MRI (RT-fMRI-NF) studies aiming at alleviating clinical symptoms in a psychiatric population; 2) a quantitative evaluation (meta-analysis) of RT-fMRI-NF effectiveness on various psychiatric disorders and 3) methodological suggestions for future studies. Thirty-one clinical trials focusing on psychiatric disorders were included and categorized according to standard diagnostic categories. Neurofeedback using (RT-fMRI-NF) is an innovative technique that allows to voluntarily modulate a targeted brain response and its associated behavior. Despite promising results in the current literature, its effectiveness on symptoms management in psychiatric disorders is not yet clearly demonstrated. Among the 31 identified studies, 22 consisted of controlled trials, of which only eight showed significant clinical improvement in the experimental vs. control group after the training. Nine studies found an effect at follow-up on ADHD symptoms, emotion dysregulation, facial emotion processing, depressive symptoms, hallucinations, psychotic symptoms, and specific phobia. Within-group meta-analysis revealed large effects of the NF training on depressive symptoms right after the training and at follow-up, as well as medium effects on anxiety and emotion regulation. Between-group meta-analysis showed a medium effect non depressive symptoms and a large effect on anxiety. However, the between-studies heterogeneity is very high. The use of RT-fMRI-NF as a treatment for psychiatric symptoms is promising, however, further double-blind, multicentric, randomized-controlled trials are warranted to determine effectiveness.

Rahmani et al. (2022) evaluated the evidence related to the effectiveness of neurofeedback treatment for children and adolescent with attention-deficit/hyperactivity disorder (ADHD). A systematic review of randomized control trials (RCTs) was carried out across multiple databases. the primary outcome measure was the most proximal ratings of ADHD symptoms in subjects. Conner's Parent Rating Scale (CPRS), Conner's Teacher Rating Scale (CTRS), and ADHD Rating Scale (ADHD-RS- are considered as primary outcomes. Seventeen trials met inclusion criteria (including 1211 patients). Analysis showed that there was no significant benefit of neurofeedback treatment compared with other treatments or control. The results provide preliminary evidence that neurofeedback treatment is not an efficacious clinical method for ADHD and suggest that more RTCs are needed to compare common treatment.

Home Biofeedback Devices

Biofeedback should be performed in a clinical setting by trained professionals. The evidence in the published peer-reviewed scientific literature does not support the effectiveness of home electronic biofeedback devices. In some instances, the results of clinical trials were limited due to the inability to monitor the use of home biofeedback used by subjects in the trial. Peirce et al. (2013) conducted a randomized controlled trial (*n*=120) to determine if home biofeedback alone would have better anal manometry results at three months postpartum compared to pelvic floor exercises (PFEs) alone in women who sustained a primary third-degree postpartum tear. The secondary outcome criterion was improvement in continence scores. Subjects were randomized to home biofeedback (*n*=30) (CombiStim XP, Neurotech®, Galway, Ireland) or conventional PFEs (*n*=90). At the 3 month follow-up, there was no significant difference in anal resting (p=0.123), squeeze pressure (p=0.68), and the Cleveland Clinic continence scores (p=0.88) between the groups. There were no significant differences in the Rockwood fecal incontinence quality of life scale score including: lifestyle (p=0.29), coping (p=0.27), depression (p=0.89) and embarrassment (p=0.51). Seven of the 30 biofeedback subjects reported poor adherence. Home biofeedback did not improve the clinical outcomes of this subpopulation of women. Limitations of the study include the small patient population and short-term follow-up.

An earlier randomized controlled trial compared the use of anorectal manometry EMG biofeedback performed in a laboratory (*n*=24) to EMG biofeedback performed in the home (*n*=12) for children with chronic constipation who had failed conventional treatment. The outcomes indicated that no additional benefit was gained by the use of home biofeedback (Croffie et al., 2005). A randomized controlled trial by Aukee et al. (2004) reported that 11 of 16 women who received 12 weeks of home EMG-assisted biofeedback (FemiScanTM, MegaElectronics, Kuopio, Finland) avoided surgical intervention compared to ten of 19 control subjects who did not use home biofeedback. In a 2002 decision memo regarding the use of home biofeedback for urinary incontinence, the Centers for Medicare and Medicaid (2002), stated that "the scientific evidence is not adequate to conclude that the use of home biofeedback devices for the treatment of urinary incontinence is clinically effective, and, therefore, is not reasonable and necessary for treating urinary incontinence or to improve the functioning of a malformed body member".

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2017).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* policy for information.

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