The effect of biofeedback interventions on pain, overall symptoms, quality of life and physiological parameters in patients with pelvic pain

A systematic review

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Summary
Background Biofeedback is recognized as an effective additive method for treating certain phenotypes of chronic pelvic pain syndrome and is a therapeutic option in other pelvic pain conditions. This review aims to evaluate evidence from the literature with a focus on the effect of biofeedback on pain reduction, overall symptom relief, physiological parameters and quality of life.

Methods A systematic literature search was conducted using the databases PubMed, MEDLINE, Embase, Cochrane Library and PEDro from inception to July 2020. Data were tabulated and a narrative synthesis was carried out, since data heterogeneity did not allow a meta-analysis. The PEDro scale and the McMaster Critical Review Form—Quantitative Studies were applied to assess risk of bias.

Results 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. Certain factors have been identified that might be relevant in improving treatment success.

Conclusions For certain indications, biofeedback has been confirmed to be an effective treatment. For other phenotypes, promising findings should be further investigated in robust and well-designed randomized controlled trials.

Keywords Pelvic floor dysfunction · Pelvic floor dyssynergia · EMG · Electromyography · Manometry

Introduction
Biofeedback therapy is an instrument-based learning process employing operant conditioning. Autonomic and neuromuscular activity is measured and visual, acoustic and verbal feedback is provided to promote the acquisition of self-control over physiological processes, which are otherwise outside awareness or under less voluntary control [1].

Pelvic pain is perceived in pelvis-related structures and organs of either men or women and may be acute or chronic. In terms of chronic pelvic pain (CPP), there is no generally accepted definition. It can be subdivided into conditions with well-defined classical pathology and those with no obvious pathology—the chronic pelvic pain syndromes (CPPS). The European Association of Urology (EAU) describes CPPS as the occurrence of CPP with no proven infection or other obvious local pathology accounting for the pain, continuous or recurrent for at least 6 months. It is often associated with symptoms suggestive of lower urinary tract, sexual, bowel, gynecological or pelvic floor dysfunction and with negative cognitive, behavioral, sexual or emotional consequences [2].

Chronic pelvic pain is a common pain condition with a worldwide prevalence of 2.1–26.6% for non-cyclic pain in women [3–5] and 2.2–9.7% in men [6].
Up to 85% of women with CPP have dysfunction of the musculoskeletal system, including spasm of the levator ani muscle [7]. Myofascial pelvic pain is a major component of CPP which is not always properly identified by healthcare providers [8]. It may be a primary or contributing source of CPP [8]. Its hallmark diagnostic indicators are myofascial trigger points in the pelvic floor musculature that refer pain to adjacent sites [8]. They are thought to occur in response to acute and chronic physical or psychosocial stress or trauma [9].

The pathophysiology of CPP is not well understood. Treatment is therefore often unsatisfactory and limited to symptom relief [7]. Several nonsurgical strategies exist that include medical, psychological, cognitive, behavioral, complementary and physical therapy [5, 7, 10]. In the case of myofascial pelvic pain in particular, a multidisciplinary team of specialists [8] and a multimodal treatment strategy are warranted. In a large proportion of patients, treatment does not necessarily result in pain relief. CPP therefore carries a significant physical, mental, and social burden for patients and puts a heavy burden on healthcare systems worldwide. Increased medical attention to identify and test effective treatment strategies is warranted [5, 7, 10, 11].

Biofeedback seems to be a promising adjuvant tool in the cognitive-behavioral treatment of somatoform disorders because it aims to enhance control over the psychophysiological processes that may be involved in these conditions [1]. Biofeedback is also one of several effective physical therapy techniques used to treat myofascial pelvic pain [8]. The recent EAU guidelines 2019 on CPP state that biofeedback is the preferred treatment for chronic anal pain and can improve the outcome of myofascial therapy as an adjuvant to muscle exercises in patients with hypertonic pelvic floor dysfunction [2]. It is considered a treatment option in type III chronic prostatitis according to the National Institutes of Health (NIH) classification [10].

Previous systematic reviews have evaluated the evidence of physiotherapy interventions in general in the management of CPP [5, 12, 13]. One review focused on the effect of biofeedback on improving symptoms of pelvic floor dysfunction in 2008 [14]. The primary aim of our review was to evaluate the effect of biofeedback interventions on subjective outcome pain, overall symptom improvement and quality of life in patients with acute or chronic pelvic pain conditions. A secondary aim was to investigate whether biofeedback interventions improved physiological parameters indicative of pelvic floor muscle tone and/or general relaxation.

### Table 1 Inclusion and exclusion criteria

| Inclusion criteria | Exclusion criteria |
|--------------------|-------------------|
| **Study design, comparison** | Any quantitative study type of primary research with exception of case studies/case series <10 participants; retrospective studies are included |
| Control interventions may include treatment as usual, no treatment, surgery, medicinal treatment, physical therapy modalities or placebo treatment | Reviews, cross-sectional studies, case reports/case series <10 participants, conference papers and abstracts, book chapters, editorials |
| **Participants** | Unconcluded studies, studies with missing outcome data |
| People with chronic pelvic pain according to the guidelines on chronic pelvic pain [2] including constipation (conditions with overactive pelvic floor dysfunction) | Studies that were published in languages other than English and German |
| People with acute pelvic pain | Pelvic organ prolapse, fecal or urinary incontinence (hypotonic pelvic floor dysfunction) |
| Males and females | |
| Children, adolescents, adults | |
| **Interventions** | No BFB-assisted training performed/BFB was not a relevant component of the treatment |
| Biofeedback as a sole intervention or as a significant component of a multimodal intervention | If only a subgroup of the study population received BFB: studies were excluded if the number of subjects in the BFB subgroup or the outcome results of this subgroup were not stated |
| Clinical (in/outpatient) setting or home-based training | Insufficiently documented BFB intervention: no information on the training extent (frequency, number of sessions or duration of a single session) or the mode of application |
| **Outcome measures** | – Pain intensity |
| Primary outcome: | – Overall symptom improvement |
| – Quality of life | – Quality of life |
| Secondary outcome: | – Physiological parameters, indicative of pelvic floor muscle tone or general relaxation |
| BFB biofeedback | – |
## Table 2  Study characteristics

| Study                          | Country  | Study design (details: see Table 8) | n of IG receiving BFB (n of whole study participants) | Drop-outs at last f/u/ excluded from analysis | Diagnose(s), symptoms: | Conclusions by authors of respective papers |
|-------------------------------|----------|------------------------------------|------------------------------------------------------|------------------------------------------------|-------------------------|------------------------------------------------|
| **Anorectal pain syndrome**   |          |                                    |                                                      |                                                |                         |                                                 |
| Chiarioni et al. 2010 [16]    | Italy    | RCT (3 arm: 3 different interventions compared) | 52 (157)                                              | n.a.                                           | Levator ani syndrome (constipation excluded) | BFB is superior to EGS and levator ani massage in pain relief. Improvements maintained for 12 months. Only patients with tenderness on rectal examination benefit. Pathophysiology of levator ani syndrome pathophysiology is similar to dysynergic defecation type constipation |
| Heah et al. 1997 [17]         | Singapore | Non-RCT, single-group (prospective) | 16 (16)                                               | 0/16 (post treatment); n.a. (later f/u)        | Levator ani syndrome     | Although BFB had a negligible effect on anorectal physiologic measurements, it was effective in pain relief, with no side effects |
| Ger et al. 1993 [18]          | USA      | Non-RCT, 3 arm, non-randomized (prospective) | 14 (60)                                               | 22/60                                          | Chronic intractable rectal pain ± coccygodynia ± constipation ± dyschezia (n= 34/60) | BFB vs. EGS vs. epidural steroid caudal block: EGS and BFB had almost the same poor results (>50% were refractory). No significant differences in rates of success or failure after any of the 3 therapeutic options, regardless of whether the option was a primary, secondary, or tertiary choice. Associated historic factors or abnormalities in anorectal physiologic studies did not influence results |
| Gilliland et al. 1997a [19]   | USA      | Non-RCT (retrospective)             | 86 (86)                                               | 11/86                                          | Chronic intractable rectal pain ± constipation (n= 30/86) | EMG-based BFB can produce alleviation of idiopathic rectal pain. Outcome was significantly improved in patients who completed the treatment schedule compared to those who self-discharged. Outcome was not influenced by patients’ ages, duration of symptoms or prior history of surgery and was not significantly related to the presence of paradoxical puborectalis contraction (EMG or defecography) |
| Grimaud et al. 1991 [20]      | France   | Non-RCT, single-group (prospective) + cross-sectional | 12 (24)                                               | 0/12                                          | Chronic idiopathic anal pain ± constipation (n= 9/12) | Chronic idiopathic anal pain is associated with abnormal anal manometric profiles (! anal canal resting pressure), probably resulting from a dysfunctioning of the striated external anal sphincter. BFB is an effective treatment for chronic idiopathic anal pain. Anorectal pain disappeared after a mean of 8 BFB sessions |
| **Constipation, dysynergic defecation** |          |                                    |                                                      |                                                |                         |                                                 |
| Chiarioni et al. 2006 [21]    | Italy    | RCT (2 arm: intervention vs. different intervention) | 54 (109)                                              | 14/109 (10/54 in BFB group)                   | Normal transit constipation due to PFD (Rome II criteria) | 5 × 30min BFB sessions are more effective than continuous polyethylene glycol in PFD dysynergia (major improvement in 80%), benefits last at least 2 years. BFB should become the treatment of choice PFD. Predictors of better response to BFB: sensation of incomplete or blocked evacuation, straining with bowel movements; predictors of poorer response: digital facilitation of defecation |
| Koutsomanis et al. 1994 [22]  | Italy    | Non-RCT, single-group (prospective) | 54 (109)                                              | 10/30                                          | Idiopathic constipation | ~50% of patients were helped by 2–6 BFB sessions, improvement persisted for ≥6–12 months. Both types of PF incoordination (inability to relax on defecation and inability to strain effectively) improved. No clear correlation between change in transit rate and symptomatic outcome |
| Chiotakakou-Fallakou et al. 1998 [23] | UK      | Non-RCT (retrospective)             | 30 (30)                                               | 0/100                                         | Chronic idiopathic slow and normal transit constipation | BFB is an effective long-term treatment for the majority of patients with idiopathic constipation unresponsive to traditional treatment (>50% improved). Patients with slow/normal transit, males/females, with/without paradoxical PF contraction benefited equally. Anorectal testing did not predict outcome |
| Battaglia et al. 2004 [24]    | UK       | Non-RCT, single-group (prospective) | 100 (100)                                             | n.a.                                          | Chronic constipation (Rome II criteria) | Patients with PFD are likely to have continued benefit from BFB, whereas its effects on slow-transit constipation seems to be maximal in short-term course. Anorectal manometric variables remained unchanged (apart from sensation threshold) in PFD group, maximum rectal tolerable volume, in slow-transit group |
| Wang et al. 2003 [25]         | Italy    | Non-RCT, single-group (prospective) | 24 (24)                                               | n.a.                                          | Chronic idiopathic constipation (Rome II criteria) | BFB has a long-term effect with no side effects for most patients (82.5%) with chronic idiopathic constipation unresponsive to traditional treatment. Patients with slow/normal transit, with/without paradoxical PF contraction benefited equally. The psychological status rather than anorectal test could predict outcome. The efficacy of the two modes of BFB was similar |
Table 2 (Continued)

| Study                  | Country   | Study design (details: see Table 6) | n of IG receiving BFB (n of whole study participants) | Drop-outs at last f/u/ excluded from analysis | Diagnose(s), symptoms: | Conclusions by authors of respective papers |
|------------------------|-----------|-------------------------------------|------------------------------------------------------|---------------------------------------------|------------------------|---------------------------------------------|
| Ba-Bai-Ke-Re et al.    | China     | RCT (2 arm: 2 different interventions) | 50 (50)                                              | 0/44                                        | Chronic obstructive constipation (Rome III criteria) | Manometric BFB-guided PF exercise is superior to oral polyethylene glycol for obstructive defecation for improving overall symptoms, pain at defecation, quality of life |
| Roy et al. 2000        | China     | Non-RCT (retrospective)              | 44 (88)                                              | n.a.                                        | Chronic idiopathic constipation (no surgery: n=25/78, hysterectomy and no change in bowel function: n=27/78, hysterectomy subjectively led to constipation: n=26/78) | The majority of patients complaining of constipation induced by hysterectomy subjectively respond to behavioral treatment, in a similar proportion to those with idiopathic constipation. Physiological testing did not predict outcome |
| Chiarioni et al. 2005  | UK        | Non-RCT, single group (prospective)  | 78 (78)                                              | 7/52                                        | Chronic idiopathic constipation (PFD: n=34/52, slow transit only: n=12/52, 1–2 criteria for PFD: n=6/52) | BFB is an effective treatment for PFD but not slow-transit constipation. Improvements were maintained at f/u 24 months. BFB eliminated dyssynergia in 91% and enabled 85% to defecate the balloon. Success was predicted by PFD, milder constipation, and less frequent abdominal pain at baseline |
| Zhu et al. 2011        | Italy     | Non-RCT single group, observational  | 41 (41)                                              | 5/41                                        | Functional constipation with PFD (Rome III criteria) | Before treatment, 7 Short Form-36 subscales (except bodily pain) were significantly lower in people with PFD than in healthy individuals. After BFB, all subcategories except general health showed improvement surpassing pretreatment baseline values and equaling those for normal. The total Patient Assessment of Constipation Quality of Life Questionnaire score also dramatically improved as did all subscales |
| Gilliland et al. 1997b | USA       | Non-RCT (retrospective)              | 194 (194)                                             | 16/194                                      | Chronic constipation ± concomitant rectal pain (n=30/194) | Success rate of BFB for constipated patients is less than previously reported (35% complete success, 13% partial success). Success rate 1 after ≥5 sessions was significantly related to patient’s willingness to complete treatment and number of sessions attended. Neither patient age, sex, abnormalities in manometry nor duration of symptoms significantly affected outcome |
| Parker et al. 2019     | Canada    | Non-RCT (retrospective)              | 130 (130)                                             | 38/168                                      | Chronic constipation + PFD (n=53/130, without PFD (n=3/130), fecal incontinence (n=49/130), constipation + fecal incontinence (n=22/130), rectal pain (n=3/130) | In patients with chronic constipation due to PFD, overall response rate was 69.8%, only 45.3% had symptomatic improvement. These patients are less likely to have symptomatic response than those without fecal incontinence. 3 BFB sessions are insufficient to manage dyssynergic defecation |

**Male chronic pelvic pain syndrome, urological chronic pelvic pain syndrome**

| Study                  | Country   | Study design (details: see Table 6) | n of IG receiving BFB (n of whole study participants) | Drop-outs at last f/u/ excluded from analysis | Diagnose(s), symptoms: | Conclusions by authors of respective papers |
|------------------------|-----------|-------------------------------------|------------------------------------------------------|---------------------------------------------|------------------------|---------------------------------------------|
| Clemens et al. 2000    | –         | Non-RCT, single group               | 19 (19)                                              | 3/19                                        | Nonbacterial male CPPS [33] (NIH type IIIB prostatitis: n=6/19, NIH type IIIB prostatitis: n=12/19) | A formalized program of neuromuscular reeducation of PF muscles with interval bladder training can provide significant, durable improvement in objective measures of pain, urgency, and frequency in patients with CPPS. Detrusor instability, hypersensitivity to filling, or bladder-sphincter pseudodyssynergia on pretreatment urodynamic studies were not predictive of treatment results |
| Cornel et al. 2005     | USA       | Non-RCT, single group; observational | 33 (33)                                              | 2/33 (15/33 for EMG values)                 | Male CPPS (NIH type III prostatitis) [33] | BFB physical therapy and PF reeducation lead to a significant symptom improvement and decrease of PF muscle tension |
| Yang et al. 2017       | Netherlands | Non-RCT (retrospective)           | 22 (50)                                              | 5/50                                        | Male CPPS (NIH type IIIB, IIIB prostatitis) [33] | Both electromagnetic stimulation and EGS + BFB physical therapy of PF muscle effectively reduce pain, increase quality of life and improve urinary tract symptoms in refractory male CPPS. EGS + BFB had additional benefits on pain and QoL compared to electromagnetic stimulation alone |
| He et al. 2010         | Taiwan    | Non-RCT (retrospective)             | 21 (21)                                              | n.a.                                        | Nonbacterial male CPPS + dysfunctional voiding | BFB had satisfactory short-term effects on patients with dysfunctional voiding and chronic prostatitis. Urodynamics could be used to help in the diagnosis and select the most appropriate treatment |
### Female chronic pelvic pain

| Study                  | Country | Study design (details: see Table 1) | n of IG receiving BFB (n of whole study participants) | Drop-outs at last f/u/ excluded from analysis | Diagnose(s), symptoms: | Conclusions by authors of respective papers |
|------------------------|---------|-------------------------------------|------------------------------------------------------|---------------------------------------------|------------------------|------------------------------------------------|
| Schmitt et al. 2017    | USA     | Non-RCT, single-group (prospective) | 94 (94)                                              | 0/94 dropouts, but missing outcome data (n: Tables 2, 3 and 4) | Pelvic pain or dyspareunia (n=29/94), defecatory symptoms (n=31/94), urinary symptoms (n=84/94) | An aggressive PF rehabilitation program including BFB with vaginal EGS had a high rate of self-reported subjective success and satisfaction in patients with PF dysfunction |
| Glazer et al. 1995     | USA     | Non-RCT, single-group (prospective) | 33 (33)                                              | n.a.                                        | Vulvar vestibulitis syndrome | PF muscle instability is a critical factor in pain associated with vulvar vestibulitis syndrome. A BFB-assisted exercise program that stabilizes PF muscles significantly reduces and, in some cases, eliminates symptoms. The more the PF muscle stabilized, the more pain decreased, the higher the initial pain, the higher the pain reduction. 6-month f/u indicated maintenance of therapeutic benefits |
| McKay et al. 2001      | USA     | Non-RCT, single-group (prospective) | 29 (29)                                              | Monthly f/u, 25/29 (3) after 11 months      | Moderate—severe vulvar vestibulitis syndrome | EMG BFB of PF is an effective approach to vulvar vestibulitis. 88.9% reported negligible or mild pain after treatment |
| Gentilcore-Saulnier et al. 2010 | Canada | Non-RCT, single-group (prospective) + cross-sectional | 11 (22)                                              | n.a.                                        | Provoked vestibulodynia ± constipation, dysmenorrhea, urinary frequency | Women with provoked vestibulodynia showed altered PF muscle behavior compared to controls, providing empirical evidence of PF muscle dysfunction, especially at the superficial layer. A physiotherapy rehabilitation program targeting PF muscle dysfunction normalized PF muscle behavior |
| Bendana et al. 2009    | USA     | Non-RCT (retrospective)             | 52 (52)                                              | 0/52 dropouts⁴                             | Painful PF spasm + urinary urgency/frequency | Combined transvaginal BFB, electrostimulation and behavioral therapy targeting PF relaxation demonstrated statistically significant improvement in urinary symptoms for up to 3 months. Further study for refractory patients is warranted |
| Phillips et al. 1992   | Canada  | RCT (randomized yoked design, intervention vs. different vs. no intervention) | 10 (30)                                              | n.a.                                        | Urethral dysmenorrhea—to functional urinary incoordination (pelvic pain: n=11/30, dyspareunia: n=9/30) | Both EMG BFB and progressive muscle relaxation proved effective in improving symptomology and psychological state in patients with functional urinary incoordination |
| Hart et al. 1981       | USA     | Non-RCT, 2 arm: 2 different interventions (prospective) | 14 (14)                                              | 3/14                                       | Spasmodic dysmenorrhea according to MSQ | BFB and temperature training are effective in reducing many of the painful symptoms of primary dysmenorrhea. There was no significant difference between EMG and temperature training |
| Bennink et al. 1982    | USA     | RCT (3 arm: intervention ± different intervention vs. no intervention) | 5 (15)                                               | 0/15                                       | Primary dysmenorrhea (spasmodic or congestive) | Subjective reports indicated that the symptoms of dysmenorrhea improved for the BFB group but not for the relaxation or control groups |
| Vagedes et al. 2019    | Germany | RCT (3 arm: 2 different interventions vs. standard care) | 20 (60)                                              | 12/60 (6/20 in BFB group) | Primary dysmenorrhea | Preliminary evidence suggests that rhythmic massage might improve pain intensity after 12 weeks compared to usual care. No significant differences were found between heart rate variability-based home-BFB and the control group |
| Starr et al. 2013      | USA     | Non-RCT (retrospective)             | 778 (778)                                            | 97/778                                    | PF-dysfunction (urinary: n=694/778, defecatory: n=167/778, pelvic pain: n=368/778) | Comprehensive PF rehabilitation including PF muscle training, BFB, EGS, constipation management, behavioral modification, incontinence devices, and pharmacotherapy is effective in treating women with PF dysfunction |
| Lucio et al. 2014      | Brazil  | RCT, (3 arm: multimodal + sham vs. local vs. distal electrotherapy) | 30 (30)                                              | 10/30                                      | Woman with multiple sclerosis + sexual dysfunction | PF muscle training with EMG BFB—alone or combined with intravaginal EGS or transcutaneous tibial nerve stimulation—contributes to the improvement of sexual dysfunction in patients with multiple sclerosis |
| Aalaie et al. 2020     | Iran    | RCT (2 arm: 2 different interventions) | 11 (22)                                              | 1/22 (in BFB group)                       | Female sexual pain dysfunction (DSM-5 criteria [49, 50], FSFI) + stress urinary incontinence | Both BFB and EGS increased the FSFI score. Both interventions decreased pain during vaginal penetration similarly. To improve sexual function, women undergoing BFB seem to benefit more than those receiving EGS |
Table 2 (Continued)

| Study                        | Country | Study design (details: see Table 8) | n of IG receiving BFB (n of whole study participants) | Drop-outs at last f/u/ excluded from analysis | Diagnose(s), symptoms:                                                                 | Conclusions by authors of respective papers                                                                 |
|------------------------------|---------|-------------------------------------|--------------------------------------------------------|---------------------------------------------|----------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| **Chronic pelvic pain in children** |         |                                     |                                                        |                                             |                                                                                        |                                                                                                    |
| Hoebeke et al. 2004 [51]     | Belgium | Non-RCT, single-group (prospective)  | 21 (21)                                                | n.a.                                        | PF spasms ± detrusor hyperactivity (n=13/21), ±dysfunctional voiding (n=5/21), ±constipation (n=8/21) | Pelvic floor spasms in children (which can be secondary to detrusor overactivity) respond well to pelvic floor relaxation therapy |
| Ebiloglu et al. 2016 [52]    | Turkey  | Non-RCT (retrospective)              | 136 (136)                                              | n.a.                                        | Overactive bladder syndrome                                                              | BFB can be thought of as the first-line treatment option when standard urotherapy fails. Success rate was 53% for urgency, 69% for dysuria. The mean LUTSS significantly improved after BFB. Patients without holding maneuvers, daytime incontinence and enuresis had better recovery compared to the opposites |
| Ergin et al. 2016 [53]       | Turkey  | Non-RCT, single-group (prospective)  | 52 (100)                                               | 46 healthy                                  | Dysfunctional voiding (n=52/100), +overactive bladder syndrome (n=27/52)                 | Urinary nerve growth factor (UNGF) levels were higher in children with dysfunctional voiding and decreased after BFB. UNGF levels could be used for the diagnosis and the assessment of BFB success in these children |
| Li et al. 2006 [54]          | China   | Non-RCT, single-group (prospective)  | 25 (40)                                                | 15 healthy                                  | Pubertal chronic prostatitis, NIH type II (n=1/25), IIIA (n=3/25), IIIB (n=21/25)     | The main type of chronic prostatitis during puberty is IIIB, the dominating symptom is a voiding disorder. The impact on life and psychological effects are substantial. Pubertal boys with chronic prostatitis have PF dysfunction and several abnormal urodynamic values. The effect of BFB in pubertal chronic prostatitis is satisfactory |

**Musculoskeletal, low back pain, myofascial pain**

| Kent et al. 2015 [55]        | Denmark | RCT (2 arm: intervention + standard care vs. placebo + standard care) | 58 (112)                                           | 19/112                                       | Subacute—chronic low back pain                                                           | Individualized movement retraining using motion-sensor biofeedback resulted in significant and sustained improvements in low back pain. This pilot trial also refined the procedures and sample size requirements for a fully powered RCT |

**BFB biofeedback, CPPS chronic pelvic pain syndrome, CP/CPPS chronic prostatitis/chronic pelvic pain syndrome, DSM-5 criteria diagnostic and statistical manual of mental disorders, EGS electrogalvanic stimulation, EMG electromyography, FSFI female sexual function index [56], f/u follow-up, IG intervention group, LUTSS lower urinary tract symptom score [57], MSQ mensural Symptom questionnaire (MSQ) [58], NIH National Institute of Health, NIH-CPSI National Institute of Health – chronic prostatitis symptom index score, PF pelvic floor, PFD pelvic floor dyssynergia, ↑ significant decrease, ↓ significant increase, RCT randomized controlled trial, vs. versus

**Methods**

**Protocol and registration**

A systematic review of the existing scientific literature was conducted, based on the guidelines recommended by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement [15]. The review protocol was registered (PROSPERO registration number: CRD42020201751).

**Identification and selection of studies**

The search included the electronic databases PubMed, Medline, Embase, PEDro and Cochrane Library. Trials with the keywords “pelvic pain AND biofeedback” were extracted and considered for inclusion. No filters were used. No restrictions were placed on the year of publication. A systematic literature search was independently performed by two researchers (BW, MS) and disagreements in selection were resolved through discussion. The process was supervised by an experienced senior researcher (RC).

**Inclusion and exclusion criteria**

Table 1 presents the inclusion and exclusion criteria regarding study design, participants, interventions and outcome evaluation. Any quantitative study type of primary research (with the exception of case studies/case series less than 10 participants) was included to present a comprehensive overview of the current literature. This approach goes along with previous reviews [5, 13] which stated that including randomized controlled trials (RCTs) only was not feasible in reviewing physiotherapy interventions in patients with CPP. We considered males and females of all ages with either acute or chronic pelvic pain conditions as listed in the EAU guidelines [2], including both specific disease-associated pelvic pain and pelvic pain syndromes. Interventions were judged eligible if biofeedback was administered as a sole intervention or significant component of a multimodal or multidisciplinary intervention (including mechanical or electrical devices), as multidisciplinary management of CPP is considered optimal [13].
Data collection and analysis

For eligible papers, the following data were extracted: study characteristics (author and year of publication, country site, study design, sample sizes, drop-out rate, diagnoses investigated, author's conclusions), patient characteristics (sample characteristics, mean duration of symptoms, sex, mean age), intervention characteristics (interventions administered, time points of follow-up, biofeedback devices, training extent, intervention setting, adverse events) (Tables 2, 3 and 4). Primary outcome parameters were pain, overall symptom improvement and quality of life. Secondly, physiological parameters were assessed. When certain data were not given in the respective studies the information was stated as “not available”.

Outcome data were presented by means of the mean difference within a study group or between groups and their statistical significance (Tables 5, 6 and 7). Few studies provided effect sizes or the corresponding interval estimates (e.g. the confidence intervals) for the mean differences. These values were calculated by the authors if studies provided the relevant data to do so. The criteria for determining effect sizes according to Cohen [61] are listed in the legend of Tables 5 and 7.

Data synthesis

An attempt was made to bundle data for a meta-analysis; however, due to the substantial heterogeneity of study designs, patient characteristics, interventions and effect measures, a meta-analysis was not possible as results are considered unreliable when a small number of heterogeneous studies are assessed [70]. Rather, a narrative synthesis of study results was performed [71], and findings were juxtaposed in the respective tables to provide a comprehensive overview of the current literature.

Quality assessment

As trials differed in their study design, the McMaster Critical Review Form—Quantitative Studies [72, 73] was chosen for assessing the methodological quality of all studies included. This critical appraisal tool allows comparisons across different types of quantitative study designs due to its generic composition [5, 74, 75]. It comprises 15 items that evaluate method rigor and bias and has a guideline for completing the questionnaire that facilitates consistency in interpretation and application [72, 74]. In its original form, the tool did not provide a numerical summation. Based on previous reviews [5, 74, 75], for better comparability between included studies, a sum score of the respective subdomains was established. Each question is rated with either “yes” (1 point), “no”, “not addressed” or “not applicable (N/A)” (0 points). In this arbitrary scoring system, higher scores indicate higher methodological quality, resulting in a possible total score of 14 points [5].

In addition, studies with an RCT design were evaluated using the Physiotherapy Evidence Database—PEDro score, a valid and reliable tool for assessing the methodological quality and completeness of statistically reporting of randomized and quasi randomized controlled trials in physiotherapy [12, 76–81]. The tool evaluates internal validity and interpretability [82]. Eleven items are rated yes or no (1 or 0 points) according to whether the criterion is clearly satisfied in the study. A total PEDro score is achieved by adding the ratings of items 2–11 for a total score between 0 and 10. Higher scores indicate superior methodological quality. Studies with 9–10 points are considered excellent, 6–8 good, 4–5 fair and <4 poor quality [80].

Results

Study selection

A total of 651 studies published between 1978 and 29 July 2020 were found and screened for eligibility by title and abstract. After eliminating duplicates, 389 studies were rejected as non-includable, 83 studies were selected for full-text analysis and 37 articles corresponded to the inclusion criteria. Details on the systematic literature search and the selection process are presented in Fig. 1.

Study characteristics

Quality assessment

Table 8 shows the quality assessment using the McMaster Critical Review Form—Quantitative Studies Tool for assessing the risk of bias of all studies included.

All studies but one were judged to have clearly stated the purpose of the study [38] and to have reviewed the relevant background literature [36]. The majority of the studies (29/37) gave enough detail on important sample characteristics. Only 10/37 studies stated how they arrived at the sample size. A minority of studies explicitly stated to have used reliable [21, 29, 34, 40, 45, 48, 55] and valid [21, 25, 26, 34, 35, 37, 40, 47, 53–55] outcome measures. For several tools, however, the psychometric properties are described in the literature. If at least one main outcome tool was used that is described in the literature, studies were marked with an asterisk. The majority of the studies (30/37) were judged to have described the intervention in detail. Where applicable/where addressed, most studies (13/14) were assessed to have avoided contamination through inadvertent treatment but not to have avoided co-interventions (17/23) as in many cases, subjects were taking medication during the study period (e.g. analgesics, laxatives in anorectal disorders). Most studies (34/37) reported results in terms of statistical significance, chose analysis methods appropriate for the study and the outcomes (32/35) and reported on drop-outs (26/37). All studies
(37/37) were assessed to have discussed the relevance of the results to clinical practice and the majority of the studies (32/37) were judged to draw appropriate conclusions, given the study methods and results. The arbitrary sum score ranged between 5 and 13 (mean 9.2).

Table 9 shows the quality assessment of the 9 RCTs according to the PEDro scale [81], resulting in 2 studies of fair [26, 55] and 7 studies of good [16, 21, 24, 44, 45, 47, 48] quality. The mean PEDro score of these studies was 6 (range 5–8). All studies were randomized (9/9), analyzed the between-group difference (9/9), reported point estimate and variability (9/9) and had similar groups at baseline (9/9). Some studies had a concealed allocation (4/9), 4 out of 9 studies reported adequate follow-up. The majority of the studies did not have blinded participants (8/9), blinded therapists (9/9) or blinded assessors (5/9). In 7 out of 9 studies all subjects for whom outcome measures were available received the treatment or control condition as allocated or, if this was not possible, data for at least one key outcome were analyzed by intention to treat [81].

Table 2 gives an overview of the characteristics of the included studies, additionally outlining study design, comparison characteristics and sample sizes.

Participants
A total of 2913 patients with pelvic pain conditions and 75 healthy subjects were included in 37 studies, of whom 2489 patients were assigned to groups receiving biofeedback. The other subjects received different treatment, no intervention or standard care (Table 4).

Table 3 (and Table 2) present the patient characteristics: 5 studies investigated patients with anorectal pain syndromes [16–20], 11 studies evaluated patients with constipation [21–31], 4 studies men with nonbacterial chronic prostatitis [32, 34–36], 12 investigated females with CPP (vulvar vestibulitis syndrome/dyspareunia, pelvic floor dysfunction, dysmenorrhea, sexual dysfunction, or urethral syndrome) [37–45, 47, 48], 1 evaluated patients with low back pain [55] and 4 studied children with pelvic floor spasm [51], overactive bladder syndrome [52], dysfunctional voiding [53] or pubertal chronic prostatitis [54]. Overlapping diagnoses were common. The literature search only revealed chronic (no acute) pelvic pain conditions treated with biofeedback. The majority of the studies (24/37) stated that a secondary cause of pelvic pain had been excluded [16–20, 22–28, 30, 32, 34–36, 38, 41, 42, 48, 52–54]. One study enrolled patients with multiple sclerosis as an underlying disease [47], 6 studies [18, 20, 23, 25, 27, 30] indicated that the included subjects suffered from some kind of psychopathology (anxiety, depression, emotional trauma), 3 studies explicitly excluded patients with a psychopathologic disorder [16, 45, 48]. A total of 15 studies [18, 20, 21, 23–28, 32, 35, 38, 39, 42, 52] stated that conventional treatment including medication, changes in diet and interventions had failed prior to biofeedback.

Age ranged between 11 and 96 years in studies mainly enrolling adults. The mean age for trials involving children was 8.4 years [51–53] and 16.5 years for the study investigating adolescents [54].

Intervention
Table 4 presents an overview of the study intervention characteristics. 27 study protocols applied biofeedback only (together with counselling/education, pelvic floor exercises and home exercises, which are counted as part of the biofeedback intervention) [17, 18, 20–32, 34, 36, 38, 39, 42–45, 48, 51, 53, 54], others applied biofeedback as a multimodal treatment component (including psychological techniques [16, 19], electrotherapy [35, 37, 40, 41, 46, 47], medication [37], manual therapy [40] or guidelines-based care [51, 55]). Most studies evaluated outcome after the treatment, some (re)evaluated 2–3 months after the end of the treatment [16, 21, 24, 26, 35, 36, 41–43, 48], some had a long-term follow-up (6–mean 28 months) [16, 18, 21–28, 32, 38, 51].

Anorectal manometric systems and surface EMG techniques were the commonly applied anorectal physiological assessment tools in studies dealing with anorectal disorders. Male chronic pelvic pain syndromes used EMG-guided training [32, 34–36]. In urogenital phenotypes in children and adolescents, both urodynamics and perineal EMG were used. In female chronic pelvic pain syndromes, most studies used pelvic floor EMG to evaluate pelvic floor function. Three studies on patients with dysmenorrhea [43–45] aimed at increasing general relaxation by using heart rate variability training, skin temperature training and EMG of the frontalis and lower abdominal muscles.

Overall, the biofeedback training extent was largely heterogeneous, 2–30 sessions were administered, lasting between 10 and 60 min, for up to 6 months. Most designs applied biofeedback weekly, less often sessions were scheduled twice or three times a week or once every 2 weeks. Biofeedback in a home-based setting was applied daily in 3 studies on gynecological disorders [38, 39, 45]. Treating anorectal disorders, four large trials by Chiarioni et al. [16, 21, 28] and Ba-Bai-Ke-Re et al. [26] proved 5 weekly biofeedback sessions of 30 min to be successful (Table 4).

Of the studies 11 reported that no biofeedback-related side effects had occurred [16–19, 21, 25, 29, 30, 35, 48, 52] and 1 study noted a transient skin irritation related to the use of a tape [55].

Outcome
Primarily evaluated outcomes: pain intensity, overall symptom improvement, quality of life

Heterogeneous assessment methods were used to evaluate primary outcome measures within a certain phenotype (Tables 5 and 7). Pain was assessed using either visual
### Table 3 Patient characteristics

| Study | Subgroups according to physiological testing (if applicable) | Mean symptom duration ± SD (range) | Sex % | Mean age IG in years ± SD (range) |
|-------|-------------------------------------------------------------|-----------------------------------|-------|-----------------------------------|
|       |                                                             |                                   | Male | Female                           |
|       |                                                             |                                   | 17.1 ± 4.3 months (“high likely” LAS), 18.6 ± 4.8 (“possible” LAS) | 19% (“high likely” LAS), 33% (“possible” LAS) | 48% | 41.0 ± 10.0 in “high likely” LAS, 41.4 ± 10.3 in “possible” LAS |
| Anorectal pain syndrome |                                                                  |                                   | 32.5 ± 6.7 months | 56.3% b | 43.6% b | 50.5 (39–66) |
| Chiarioni et al. 2010 [16] | n.a.                                                      |                                   | 54 (2–228) months | 42.9% b | 57.1% b | 71 (n.a.) |
| Heah et al. 1997 [17] | n.a.                                                      |                                   | 36 (3-lifelong) months | 36.0% b | 64.0% b | 68 (12–96) |
| Ger et al. 1993 [18] | High resting pressures (manometry): n = 5/14, non-relaxation or paradoxical PF contraction: n = 7/14, abnormal cinedefecography: n = 14/14 |                                   |                                   |                                   |                                   |
| Gilliland et al. 1997a [19] |                                                                  |                                   | 8 ± 6 (3–72) months | 66.7% b | 33.3% b | 54 ± 3 (24–66) |
| Constipation, dyssynergic defecation |                                                                  |                                   | 368 (4–80) months | 05.8% b | 94.2% b | 34.9 ± 10.2 (23–63) |
| Chiarioni et al. 2006 [21] | Slow transit constipation was excluded | >12 months | 5.6% b | 94.4b | 33.3 ± 1.5b |
| Koutsomanis et al. 1994 [22] | Slow transit: n = 2/20, slow transit + pelvic incoordination: n = 11/20, pelvic incoordination: n = 7/20 | n.a. | 90.0% b | 10.0% b | 34 (18–53) |
| Chiotakakou-Faliakou et al. 1998 [23] | Slow transit: n = 18/100, slow transit + paradoxical PF contraction: n = 20/100, normal transit: n = 11/100, normal transit + paradoxical PF contraction: n = 15/100 | n.a., median age of onset: 21 (0–70) | 13.0% b | 87.0% b | 40 (10–79) |
| Battaglia et al. 2004 [24] | PF dyssynergia, n = 14/24, slow transit: n = 10/24 | >12 months | 16.7% b | 83.3% b | n.a., (27–54) |
| Wang et al. 2003 [25] | Slow transit: n = 8/50, anorectic outlet obstruction: n = 36/50, both: n = 6/50 | 55.2 (30–360) months | 28.0% b | 72.0% b | 52.6 (16–71) |
| Ba-Bai-Ke-Re et al. 2014 [26] | n.a.                                                      |                                   | 42 months | n.a. | n.a. | 54 (n.a.) |
| Roy et al. 2000 [27] | Rectal prolapse: n = 12/78, rectoceles: n = 22/78, slow transit: n = 53/78, paradoxical PF contraction: n = 40/78 | Several years | 0% b | 100% b | n.a. (24–75) |
| Chiarioni et al. 2005 [28] | n.a.                                                      | 168 (24–480) months | 05.8% b | 94.2% b | 34.9 ± 10.2 (23–63) |
| Zhu et al. 2011 [29] | n.a.                                                      |                                   | 38.9% b | 61.1% b | 46.4 (21–65) |
| Gilliland et al. 1997b [30] | Fixed or dynamic descent: n = 100/194, rectoceles: n = 32/194, intussusception: n = 15/194 | 168 (2–lifelong) months | 30.4% b | 69.6% b | 71 (11–96) |
| Parker et al. 2019 [31] | Chronic constipation + dyssynergic defecation n = 53/130, without: n = 3/130 | n.a. | 20.8% b | 79.2% b | 57.5 ± 16.4 b |
| Male chronic pelvic pain syndrome, urological chronic pelvic pain syndrome |                                                                  |                                   |                                  |                                  |                                  |
| Clements et al. 2000 [32] | Detrusor instability: n = 5/19, diminished bladder capacity: n = 4/19, dysfunctional voiding of bladder (pseudodyssynergia): n = 6/19, cystometric abnormalities + pseudodyssynergia n = 3/19 | ≥3 months | 100% b | 0% b | 38 (18–67) |
| Cornet et al. 2005 [34] | n.a.                                                      |                                   | 30.4 (6–144) months | 100% b | 0% b | 45 (23–70) |
| Yang et al. 2017 [35] | n.a.                                                      |                                   | >3 months | 100% b | 0% b | 43.4 (24–68) |
| He et al. 2010 [36] | n.a.                                                      |                                   | >3 months | 100% b | 0% | n.a. |
Table 3 (Continued)

| Study                        | Subgroups according to physiological testing (if applicable) | Mean symptom duration ± SD (range) | Sex %                      | Mean age IG in years ± SD (range) |
|------------------------------|-------------------------------------------------------------|-----------------------------------|----------------------------|----------------------------------|
|                              |                 |                                   | Male | Female |                                   |                                   |
| **Female chronic pelvic pain**|                 |                                   |      |        |                                   |                                   |
| Schmitt et al. 2017 [37]     | n.a.            | n.a.                              | 0%   | 100%   | 52.2 ± 15.4 in n= 29 with pelvic pain |
| Glazer et al. 1995 [38]      | n.a.            | 40.8 (24–72) months               | 0%   | 100%   | 31.5 (21–45)                     |
| McKay et al. 2001 [39]       | n.a.            | 44.4 (24–60) months               | 0%   | 100%   | 35 (25–48)                       |
| Gentilcore-Saulnier et al. 2010 [40] | n.a. | 48 ± 12 months                  | 0%   | 100%   | 22 ± 2                           |
| Bendana et al. 2009 [41]     | n.a.            | n.a.                              | 0%   | 100%   | 45.0 ± 17, (19–76)               |
| Phillips et al. 1992 [42]    | n.a.            | 57 (4–240) months                | 0%b  | 100%b  | 25.7 ± 4.7b                     |
| Hart et al. 1981 [43]        | n.a.            | n.a.                              | 0%   | 100%   | 26 ± 6.2                         |
| Bennink et al. 1982 [44]     | n.a.            | n.a.                              | 0%4  | 100%4  | 19.2 (n.a.)4                     |
| Vagedes et al. 2019 [45]     | n.a.            | >1 year                           | 0%a  | 100%a  | 29.7 ± 8.0a                     |
| Starr et al. 2013 [46]       | n.a.            | n.a.                              | 0%b  | 100%b  | 51 (18–95)b                      |
| Lúcio et al. 2014 [47]       | n.a.            | 4.1 (0.7–10) months              | 0%b  | 100%b  | 44.5 (36–51)b in intervention group 1 |
| Aalaie et al. 2020 [48]      | n.a.            | n.a.                              | 0%   | 100%   | 50.7 ± 6.1                       |
| **Chronic pelvic pain in children** |                 |                                   |      |        |                                   |                                   |
| Hoebeke et al. 2004 [51]     | n.a.            | 3 months                          | 9.5% | 90.5%  | 8.3 (n.a.)                       |
| Ebiloglu et al. 2016 [52]    | n.a.            | Overactive bladder syndrome + dysfunctional voiding: n= 107/136, overactive bladder syndrome only: n= 29/136 | n.a. | 29.0%b | 71.0%b | 8.11 (5–14)b |
| Ergin et al. 2016 [53]       | n.a.            | n.a.                              | 23.1%b | 76.9%b | 8.84 ± 2.54b                     |
| Li et al. 2006 [54]          | n.a.            | >3 months                         | 100%b | 0%     | 16.5 ± 1.1 (15–18)b              |
| **Musculoskeletal, low back pain, myofascial pain** | |                                   |      |        |                                   |                                   |
| Kent et al. 2015 [55]        | n.a.            | 13 (4.25–13) months              | 48.0%b | 52.0%b | 39 ± 12b                         |
| *LAS levator ani syndrome, n.a. data not available, PF pelvic floor, IG intervention group, BFB biofeedback* | | | | | |
| *all study patients* | | | | | |
| *patients in IG receiving BFB* | | | | | |

analog scale (VAS) or numeric rating scale (NRS) [16, 17, 32, 35, 37–40, 45, 55, 60] or subdomains of relevant questionnaires [29, 34–36, 47, 48, 54]. In terms of overall symptom improvement, several studies used symptom scores [26, 32, 34–36, 41, 43, 44, 47, 48, 52–54]. Apart from using standardized questionnaires, many studies reported the success rate, given as the number or percentage of patients who stated subjective pain or symptom improvement. Definitions regarding the extent of symptom improvement differed between studies (Tables 5, 6 and 7).

Quality of life was only assessed in 9 studies [26, 29, 34–36, 40, 41, 45, 54], applying questionnaires, subdomains of validated symptom scores or impact on quality of life on a VAS or NRS scale [60].

Outcome tools together with references of the respective questionnaires are outlined in Tables 5 and 7.

**Secondarily evaluated outcomes: physiological parameters** Pelvic floor function was assessed using manometric devices, urodynamical devices as well as surface EMG techniques and digital examination. One study observed general relaxation through heart rate variability measures [45].

**Effect of biofeedback interventions on pain, overall symptoms**

Table 5 presents the effect of biofeedback-assisted interventions on pain and overall symptom improve-
### Table 4 Intervention characteristics

| Study | Interventions performed in longitudinal study arm | Time points of follow-up | BFB device details | BFB treatment details: number of sessions, duration per session (min/), frequency (times/week), duration of whole intervention (weeks, if available) | Setting of BFB intervention (clinical/home-based), home exercise (=HE) encouraged (yes/not addressed) |
|-------|-----------------------------------------------|-------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| **Anorectal pain syndrome** | | | | | |
| Chiarioni et al. 2010 [16] | IG 1: BFB + psychological counselling (5 sessions BFB + 4 sessions psychological counselling) (n = 52) | Baseline, 1, 3, 6, 12 months | Anal sEMG probe | 5 sessions, 30 min, 1 ×/week | Clinical |
| | IG 2: EGS (9 sessions, 30–45 min, 3 ×/week) + 4 sessions psychological counselling (n = 52) | Baseline, 1, 3, 6, 12 months | – | – | – |
| | IG 3: massage of levator ani muscle (9 sessions, 30–45 min, 3 ×/week) + 4 sessions psychological counselling (n = 53) | Baseline, 1, 3, 6, 12 months | – | – | – |
| Heath et al. 1997 [17] | BFB | Baseline—2 weeks after treatment, mean f/u 12.8 ± 2.6 months | Anorectal manometry (rectal balloon) | 4 sessions, 60 min, 1 ×/week | Clinical (HE: yes) |
| Ger et al. 1993 [18] | IG 1: EGS (3 sessions, 30–60 min, 7–10 days) (some had failed BFB, epidural caudal block earlier) | Baseline—mean f/u 15 [2–36] months after treatment | – | – | – |
| | IG 2: BFB (50% had failed EGS earlier) | Same as IG1 | Anal sEMG probe | ≥6 sessions, 30–60 min, 1 ×/week | Clinical (HE: yes) |
| | IG 3: epidural steroid caudal block (some had failed other modalities earlier) | Same as IG1 | – | – | – |
| Gilliland et al. 1997a [19] | BFB including education, stress management and cognitive-behavioral psychotherapy techniques | Baseline—after treatment (time-points varied) | Anal sEMG probe | 2–18 sessions (until improvement/persistent failure/self-discharge), 60 min; frequency n.a. | Clinical (HE: yes) |
| Grimaud et al. 1991 [20] | BFB + education | Baseline—after treatment, long term f/u after 16 ± 1 [10–24] months | Anorectal manometry | 5–13 sessions, 30 min, 1 ×/week until pain disappearance (8 ± 1 [5–13] weeks), reeducation sessions over 6 months | Clinical (HE: yes) |
| **Constipation, dyssynergic defecation** | | | | | |
| Chiarioni 2006 [21] | IG1: BFB | Baseline, 6, 12, 24 months after starting treatment | Anal sEMG probe | 5 sessions, 30 min, 1 ×/week | Clinical, laxatives at home |
| | IG2: laxatives (polyethylene glycol 1–2 packets daily + counselling with physician) | Same as IG1 | – | – | – |
| Koutsomanis et al. 1994 [22] | BFB | Baseline, after treatment, 6 weeks after starting treatment, 6–12 months after 6-week f/u | sEMG skin electrodes close to anal verge (external anal sphincter), visual + acoustic feedback | Mean 4 [2–6] sessions (until improvement or persistent failure), 30–45 min, 1 ×/week | Clinical (HE: n.a.) |
| Chiotakakou-Faliakou et al. 1998 [23] | BFB + education, balloon defecation training | Baseline, after treatment, long term f/u (mean 23.4 [12–44] months after treatment) | sEMG skin electrodes close to anal verge (external anal sphincter), visual feedback | Mean 4 [1–10] sessions, duration n.a., 1 ×/1–2 weeks | Clinical (HE: yes) |
| Battaglia et al. 2004 [24] | BFB + balloon defecation training | Baseline, 3 months, 1 year after treatment | Anal sEMG plug | 8 sessions, duration n.a., 2 ×/week, over 4 weeks | Clinical (HE: yes) |
### Table 4 (Continued)

| Study/Author               | Intervention Description                                                                 | Time points of follow-up               | BFB device details                                                                 | BFB treatment details: number of sessions, duration per session (min.), frequency (times/week), duration of whole intervention (weeks, if available) | Setting of BFB intervention (clinical/home-based), home exercise (HE) encouraged (yes/not addressed) |
|----------------------------|--------------------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Wang et al. 2003 [25]      | BFB: EMG vs. manometry based BFB                                                           | Baseline, after treatment, long term f/u (mean 18 [12–26] months after treatment) | EMG based BFB: surface sEMG electrodes (anal sphincter), auditory + visual feedback; manometry based BFB: visual BFB | 5 sessions, 30 min, 1 ×/week                                                                                                                     | Clinical (HE: yes)                                                                                      |
| Ba-Bai-Ke-Re et al. 2014 [26] | IG2: laxatives (polyethylene glycol, 17 g 3 ×/day, 2 weeks)                                 | 6–8 sessions, 1 ×/week, later        | sEMG skin electrodes close to anal verge (external anal sphincter), visual feedback | 4–5 sessions, duration n.a. 1/1–2 week                                                                                                           | Clinical (HE: n.a.)                                                                                     |
| Roy et al. 2000 [27]       | BFB                                                                                        | Baseline, after treatment, long term f/u (mean 28 [12–44] months after treatment) | Anal sEMG plug, visual feedback                                                   | 5 sessions, 30–45 min, 1 ×/week                                                                                                                 | Clinical (HE: n.a.)                                                                                     |
| Chiarioni et al. 2005 [28] | BFB + balloon defecation training                                                          | Baseline, 1, 6, 12, 24 months after treatment | Anal sEMG probe                                                                  | 6–10 sessions, 30–60 min, frequency n.a., over 4–8 weeks                                                                                     | Clinical (HE: yes)                                                                                     |
| Zhu et al. 2011 [29]       | BFB                                                                                        | Baseline—after treatment (n.a.)       | Water-perfused intra-anal instrument, visual + verbal feedback                   | 2–4 weeks, 69–86 min, frequency n.a., over 6 months, baseline–6 months                                                                     | Clinical (HE: yes)                                                                                     |
| Gilliland et al. 1997b [30]| BFB (+education, stress management, lifestyle modification)                             | Baseline—after treatment (n.a.)       | Anal sEMG probe                                                                  | 2–6 sessions, 20–35 days, frequency n.a., over 12 weeks                                                                                  | Clinical (HE: yes)                                                                                     |
| Parker et al. 2019 [31]    | BFB (+education, exercise instructions, diet)                                              | Baseline—after treatment (n.a.)       | Anorectal manometry, visual feedback                                             | Mean 2.9 [2–3] sessions, further data n.a.                                                                                                    | Clinical (HE: yes)                                                                                     |

#### Male chronic pelvic pain syndrome, Urological Chronic Pelvic Pain Syndrome

| Study/Author               | Intervention Description                                                                 | Time points of follow-up               | BFB device details                                                                 | BFB treatment details: number of sessions, duration per session (min.), frequency (times/week), duration of whole intervention (weeks, if available) | Setting of BFB intervention (clinical/home-based), home exercise (HE) encouraged (yes/not addressed) |
|----------------------------|--------------------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Clemens et al. 2000 [32]   | BFB (PF-reduction + bladder training)                                                      | Baseline—mean 5.8 [1.6–14.8] months after treatment | sEMG electrodes                                                                  | ≤6 sessions, 60 min, 1 ×/2 week                                                                                                               | Clinical (HE: yes)                                                                                      |
| Cornell et al. 2005 [34]   | BFB                                                                                        | Baseline—after treatment (n.a.)       | Anal sEMG probe                                                                  | 6–8 sessions, 1 ×/week, later 1 ×/2–4 weeks, duration n.a.                                                                                   | Clinical (HE: n.a.)                                                                                     |
| Yang et al. 2017 [35]      | IG 1: EGS + BFB                                                                            | Baseline—12 weeks after treatment     | Anal sEMG probe                                                                  | 8 sessions, 45 min (15 min BFB, 30 min EGS), 1–2 ×/week, over 6 weeks                                                                   | Clinical (HE: n.a.)                                                                                     |
|                            | IG 2: electromagnetic stimulation (18 sessions, 30 min, 3 ×/week, 6 weeks)                | Baseline—12 weeks after treatment     | Anal sEMG plug, visual feedback                                                  | 2–4 weeks, 69–86 min, frequency n.a., over 6 months, baseline–6 months                                                                     | Clinical (HE: yes)                                                                                     |
| He et al. 2010 [36]        | BFB                                                                                        | Baseline—10 weeks after treatment     | Anal sEMG probe                                                                  | No. sessions n.a., 30 min, 2–3 ×/week, over several weeks                                                                                 | Clinical (HE: n.a.)                                                                                     |

#### Female chronic pelvic pain

| Study/Author               | Intervention Description                                                                 | Time points of follow-up               | BFB device details                                                                 | BFB treatment details: number of sessions, duration per session (min.), frequency (times/week), duration of whole intervention (weeks, if available) | Setting of BFB intervention (clinical/home-based), home exercise (HE) encouraged (yes/not addressed) |
|----------------------------|--------------------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Schmitt et al. 2017 [37]   | BFB + vaginal EGS + behavioral modification + pharmacologic therapies for urinary and defecatory management | Baseline, after 1st, 3rd, final treatment session | sEMG skin electrodes (abdominals), vaginal/rectal sEMG probe | 4–7 sessions (until ≥ 80% improvement), BFB + 30 min vaginal EG, 1 ×/2 week                                                                 | Clinical (HE: yes)                                                                                     |
| Glazer et al. 1995 [38]    | BFB                                                                                        | Baseline, t/u at 6 clinical evaluation appointments + 6 months after 6th reevaluation | sEMG portable vaginal probe, visual feedback                                      | 20 min, 2 ×/day, 7 ×/week, after 6 evaluations: exercises continued without BFB ≥ 3 months                                                   | Home-based, 6 × clinical t/u                                                                       |
| McKay et al. 2001 [39]     | BFB                                                                                        | Baseline, t/u every 4 weeks            | sEMG portable vaginal probe, visual feedback                                      | No. sessions n.a., duration n.a., 60 repetitions, 2 ×/day, 7 ×/week, up to 11 months                                                            | Home-based, 1 ×/4 weeks clinical t/u                                                               |
| Gentilcore-Sauvnier et al. 2010 [40] | BFB + education, manual therapy, EGS, dilator insertion                                | Baseline—after treatment (n.a.)       | sEMG vaginal probe (deep PF), sEMG electrodes (superficial PF) | 8 sessions, 60–75 min overall (10–15 min BFB), frequency n.a., over 12 ± 3 weeks                                                               | Clinical (HE: yes)                                                                                     |
| Bendana et al. 2009 [41]   | BFB + education, vaginal EGS                                                              | Baseline, after treatment, 3 months after treatment | sEMG vaginal probe                                                                | 6 sessions, 60 min (10 min BFB, 20 min EGS), 1 ×/week                                                                                       | Clinical (HE: n.a.)                                                                                     |
| Study               | Interventions performed in longitudinal study arm                                      | Time points of follow-up                                           | BFB device details                  | BFB treatment details: number of sessions, duration per session (min, frequency) (times/week), duration of whole intervention (weeks, if available) | Setting of BFB intervention (clinical/home-based), home exercise (HE) encouraged (yes/not addressed) |
|--------------------|----------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Philips et al.     | IG1: BFB (± retention control/pain management techniques)                                | Baseline, after treatment, 2 months after treatment                | Perivaginal sEMG electrodes, visual feedback | Mean 8 [5–12] sessions (until aim reached), further data n.a.                                                                   | Clinical (HE: yes)                                                                                |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | IG2: progressive muscle relaxation (± retention control/pain management), session number same as yoked partner in BFB group | Same as IG1                                                        |                                     |                                                                                                                                  |                                                                                                   |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | Comparison group: no intervention (cross-over after 2 months)                          | Same as IG1                                                        |                                     |                                                                                                                                  |                                                                                                   |
| Hart et al.        | IG1: EMG general relaxation BFB                                                        | Baseline, after treatment (8 weeks), 8 weeks after treatment       | sEMG electrodes frontalis muscle, aural feedback                        | Mean: 12.9 [9–15] sessions, 30 min, 2 ×/week, over 2 menstrual cycles                                                        | Clinical (HE: yes)                                                                                |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | IG2: temperature general relaxation BFB                                               | Same as IG1                                                        | Skin temperature, visual + aural feedback                               | Same as IG1                                                                                                      | Same as IG1                                                                                       |
| Bennink et al.     | IG1: BFB + general relaxation                                                          | Baseline (interview), after first menstrual cycle (before treatment) and ~1 week after 3rd or 4th cycle (post treatment) | sEMG electrodes (lower abdomen), aural feedback                              | 5 sessions, 30 min, 3 sessions before, 2 sessions on first 2 days of period                                                | Clinical (HE: yes)                                                                                |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | IG2: same general and PF relaxation training without BFB                              | Same as IG1                                                        |                                     |                                                                                                                                  |                                                                                                   |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | CG: no intervention                                                                   | Same as IG1                                                        |                                     |                                                                                                                                  |                                                                                                   |
| Vagedes et al.     | IG1: BFB—slow breathing technique (general relaxation)                                 | Baseline—after treatment (n.a.)                                    | Heart rate variability Giu (Biosign) device, visual feedback               | 15 min/day, 7 ×/week, over 12 weeks                                                                                       | Home-based, clinical f/u after 1, 3, then every 4 weeks                                           |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | IG2: rhythmical massage (anthroposophic medicine) 30–45 min, 1 ×/week, 3 months       | Same as IG1                                                        |                                     |                                                                                                                                  |                                                                                                   |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | CG: standard care (analgesics, physical exercise, warmth)                              | Same as IG1                                                        |                                     |                                                                                                                                  |                                                                                                   |
| Starr et al.       | Complex PF rehabilitation: instruction, behavioral management, EGS, BFB                | 2nd BFB treatment—after treatment (12 weeks)                       | sEMG electrodes (abdominals), vaginal sEMG probe, anorectal manometry      | 5–8 sessions (8 if improvement < 80% after 5 sessions), 1 ×/2 weeks                                                          | Clinical (HE: yes)                                                                                |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | IG1: BFB + PF muscle training + placebo EGS                                           | Baseline—after treatment                                           | sEMG vaginal probe                                                          | 24 sessions, 30 min, 2 ×/week, 12 weeks                                                                                       | Clinical (HE: yes)                                                                                |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | IG2: BFB + PF muscle training + vaginal EGS (30 min, 2 ×/week, 12 weeks)               | Same as IG1                                                        |                                     |                                                                                                                                  |                                                                                                   |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | IG3: BFB + PF muscle training + transcutaneous tibial nerve stimulation (30 min, 2 ×/week, 12 weeks) | Same as IG1                                                        |                                     |                                                                                                                                  |                                                                                                   |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | Aalaie et al.                                                                          | IG1: BFB, 100 min, 2 ×/week, 6 weeks + Kegel exercises at home    | sEMG vaginal probe                                                          | 12 sessions, 100 min, 2 ×/week, over 6 weeks                                                                                      | Clinical (HE: yes)                                                                                |
|                    |                                                                                       |                                                                     |                                     |                                                                                                                                  |                                                                                                   |
|                    | IG2: vaginal EGS (50 min of stimulation, 2 ×/week, 6 weeks) + Kegel exercises at home | Same as IG1                                                        |                                     |                                                                                                                                  |                                                                                                   |
ment in detail. To provide a better overview, the main conclusions drawn by the respective authors are additionally subsumed in Table 2.

Only three [16, 17, 19] out of five studies evaluating anorectal pain syndrome provided $p$-values for pain outcomes. Significant anorectal pain relief could be shown, whereby patients who finished had superior results compared to those who discharged themselves before completion of treatment [19]. A large RCT of good quality by Chiarioni et al. 2010 found biofeedback to be superior to electrogalvanic stimulation, with medium to huge effect sizes in Yang et al. [22–24, 27, 29, 31] and constipation symptoms [22, 23, 25, 27, 29, 31] improved after biofeedback, at least for certain subgroups. Studies showed contradictory results regarding the question of whether biofeedback only benefited patients with PF dysynergia or also patients with prolonged transit time. Some studies found that biofeedback improved (long term) symptoms for pelvic floor dysynergia [22, 24, 28] but not for slow transit constipation [24, 28], others found that both phenotypes benefited equally from treatment [23, 25, 27].

With respect to the 11 studies on female chronic pelvic pain, several could improve pain [37–40, 48] or symptoms [38, 39, 41, 43, 44, 46–48], at least in the longer term. Again, several studies lacked $p$-values or measures of clinical relevance.

The 4 urogenital studies on children and adolescents and 4 studies on men with chronic prostatitis mostly found improvements in pain [32, 34–36, 51, 52, 54] and urological symptoms [32, 34–36, 52–54], with medium to huge effect sizes in Yang et al. [35].

**Effect of biofeedback interventions on quality of life**

Nine studies used biofeedback to improve pelvic floor function and found a significant improvement in the...
### Table 5  Primary outcome: effect on pain and overall symptoms

| Study          | n (total) | Group 1 (n1) | Group 2 (n2) | Outcome measure                                                                 | Mean difference: Group 2 minus Group 1 (CI) | Effect size [strength] | P-value (for difference in means) |
|----------------|-----------|--------------|--------------|---------------------------------------------------------------------------------|---------------------------------------------|------------------------|-----------------------------------|
| **Anorectal pain syndrome** |           |              |              |                                                                                 |                              |                        |                                   |
| Chiarioni et al. 2010 [16] | 104       | IG1 (BFB) in pat. w LAS (52) | IG2 (EGS) in pat. w LAS (52) | SR: % pat. w adequate pain relief after 1 month                               | −26.9                        | n.a. | p < 0.01 f                      |
|                | 104       | IG1 (BFB) in pat. w LAS (52) | IG2 (EGS) in pat. w LAS (52) | SR: % pat. w adequate pain relief after 3 months                               | −18.9                        | n.a. | p < 0.01 f                      |
|                | 104       | IG1 (BFB) in pat. w LAS (52) | IG2 (EGS) in pat. w LAS (52) | SR: % pat. w adequate pain relief after 6 months                               | −31.2                        | n.a. | p < 0.01 f                      |
|                | 104       | IG1 (BFB) in pat. w LAS (52) | IG2 (EGS) in pat. w LAS (52) | SR: % pat. w adequate pain relief after 12 months                              | −31.2                        | n.a. | p < 0.01 f                      |
|                | 105       | IG1 (BFB) in pat. w LAS (52) | IG3 (massage) in patients with LAS (52) | SR: % pat. w adequate pain relief after 1 month                               | −31.3                        | n.a. | p < 0.01 f                      |
|                | 105       | IG1 (BFB) in pat. w LAS (52) | IG3 (massage) in patients with LAS (53) | SR: % pat. w adequate pain relief after 3, 6, 12 months                          | −36.9                        | n.a. | p < 0.01 f                      |
|                | 104       | BFB in pat. w “high likely” LAS (n.a.) | EGS in pat. w “high likely” LAS (n.a.) | SR: % pat. w adequate pain relief after 1, 3, 6, 12 months                          | In favour of BFB group | n.a. | p < 0.025 f                      |
|                | 105       | BFB in pat. w “high likely” LAS (n.a.) | Massage in pat. w “high likely” LAS (n.a.) | Subjective change in pain to baseline, ordinal scale [−2 to +3: “a lot worse” to +3 “a lot better/cured”] after 1, 3, 6 months | In favour of BFB group | n.a. | p < 0.025 d                      |
|                | 104       | BFB in pat. w “possible” LAS (n.a.) | EGS in pat. w “possible” LAS (n.a.) | SR: % pat. w adequate pain relief after 1, 3, 6, 12 months                          | −                      | n.a. | p < 0.025 f                      |
|                | 105       | BFB in pat. w “possible” LAS (n.a.) | Massage in pat. w “possible” LAS (n.a.) | −                                                                          | n.a. | p < 0.025 d                      |
|                | 104       | BFB in pat. w “high likely” LAS (n.a.) | EGS in pat. w “high likely” LAS (n.a.) | Subjective change in pain to baseline, ordinal scale [−2 to +3: “a lot worse” to +3 “a lot better/cured”] after 1, 3, 6 months | In favour of BFB group | n.a. | p < 0.025 d                      |
|                | 105       | BFB in pat. w “high likely” LAS (n.a.) | Massage in pat. w “high likely” LAS (n.a.) | −                                                                          | n.a. | p < 0.025 d                      |
|                | 104       | BFB in pat. w “possible” LAS (n.a.) | EGS in pat. w “possible” LAS (n.a.) | −                                                                          | n.a. | p < 0.025 d                      |
|                | 105       | BFB in pat. w “possible” LAS (n.a.) | Massage in pat. w “possible” LAS (n.a.) | −                                                                          | n.a. | p < 0.025 d                      |
|                | 104       | BFB in pat. w “high likely” LAS (n.a.) | EGS in pat. w “high likely” LAS (n.a.) | Number of days/months with rectal pain as stated in symptom log (0–30 days) after 1, 3, 6 months | In favour of BFB group | n.a. | p < 0.025 d                      |
|                | 105       | BFB in pat. w “high likely” LAS (n.a.) | Massage in pat. w “high likely” LAS (n.a.) | −                                                                          | n.a. | p < 0.025 d                      |
|                | 104       | BFB in pat. w “possible” LAS (n.a.) | EGS in pat. w “possible” LAS (n.a.) | −                                                                          | n.a. | p < 0.025 d                      |
|                | 105       | BFB in pat. w “possible” LAS (n.a.) | Massage in pat. w “possible” LAS (n.a.) | −                                                                          | n.a. | p < 0.025 d                      |
|                | 104       | BFB in pat. w “high likely” LAS (n.a.) | EGS in pat. w “high likely” LAS (n.a.) | Pain: VAS (0–10 cm), average value of worst pain/wk, after 1, 3, 6 months                  | In favour of BFB group | n.a. | p < 0.025 d                      |
|                | 105       | BFB in pat. w “high likely” LAS (n.a.) | Massage in pat. w “high likely” LAS (n.a.) | −                                                                          | n.a. | p < 0.025 d                      |
|                | 104       | BFB in pat. w “possible” LAS (n.a.) | EGS in pat. w “possible” LAS (n.a.) | −                                                                          | n.a. | p < 0.025 d                      |
|                | 105       | BFB in pat. w “possible” LAS (n.a.) | Massage in pat. w “possible” LAS (n.a.) | −                                                                          | n.a. | p < 0.025 d                      |
| Heah et al. 1997 [17] | 16        | Study group pre-BFB (16) | Study group post-BFB (16) | Pain VAS (0–10)                                                              | −6                           | n.a. | p < 0.02                        |
|                | 16        | Study group pre-BFB (16) | Study group post-BFB (16) | SR: % pat. needing analgesics                                                  | −87.5                        | n.a. | p < 0.03                        |
| Ger et al. 1993 [18] | 14        | n/a | IG2 (BFB group) post-BFB (14) | SR: % pat. w complete pain relief                                              | 14.3                         | n.a. |                             |
|                | 14        | n/a | IG2 (BFB group) post-BFB (14) | SR: % pat. w improved pain frequency/intensity                                 | 28.6                         | n.a. |                                  |
|                | 14        | n/a | IG2 (BFB group) post-BFB (14) | SR: % pat. w no improvement                                                    | 57.1                         | n.a. |                                  |
Table 5 (Continued)

| Study                                      | n (total) | Group 1 (n1)                                           | Group 2 (n2)                                           | Outcome measure                                                                 | Mean difference: Group 2 minus Group 1 [CI] | Effect size [strength] | p-value (for difference in means) |
|--------------------------------------------|-----------|--------------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------------------------------|---------------------------------|------------------------|---------------------------------|
| Gilliland et al. 1997a [19]                | 75        | BFB in pat. w rectal pain only (47)                    | BFB in pat. w rectal pain and constipation (28)        | SR: % patients reporting symptom improvement                                     | –4.02                           | n.a.                    | p = 0.81                        |
|                                            | 46        | BFB subgroup of Group 1: pat. who finished trial (7)   | BFB subgroup of Group 1: self-discharged early (39)    |                                                                                  | –57.5                           | n.a.                    | p < 0.01                        |
|                                            | 28        | BFB subgroup of Group 2: pat. who finished trial (n.a.)| BFB subgroup of Group 2: self-discharged early (n.a.)  |                                                                                  | –46.7                           | n.a.                    | p < 0.05                        |
|                                            |           |                                                        |                                                        | Conspit, dyssynergic defecation                                                  |                                 |                        |                                 |
| Chiarioni et al. 2006 [21]                 | 54        | IG1 (BFB) pre-treatment (54)                           | IG1 (BFB) 6 months after starting treatment (54)        | Frequency of abdominal pain/wk (symptom diary)                                  | –0.89 [-0.74;–0.64]              | –5.86 [H]               | p < 0.01                       |
|                                            | 54        | IG1 (BFB) pre-treatment (54)                           | IG1 (BFB) 12 months after starting treatment (54)      |                                                                                  | –0.68 [-0.73;–0.63]              | –5.78 [H]               | p < 0.01                        |
|                                            | 109       | IG1 (BFB) 6 months after starting treatment (54)        | IG2 (laxatives) 6 months after starting treatment (55)  | SR: % patients reporting symptom improvement (4 out of a scale 0–4)              | –0.63 [0.57;0.69]                | 4.85 [H]                | p < 0.01                       |
|                                            | 109       | IG1 (BFB) 6 months after starting treatment (54)        | IG2 (laxatives) 12 months after starting treatment (55) |                                                                                  | 0.58 [0.52;0.64]                | 4.26 [H]                | p < 0.01                       |
|                                            | 109       | IG1 (BFB) 6 + 12 months after starting treatment (54)   | IG2 (laxatives) 6 + 12 months after starting treatment (55) |                                                                                  | –57.8                           | n.a.                    | n.a.                           |
|                                            | 54        | n/a                                                    | IG1 (BFB) 6 + 12 months after starting treatment (54)   |                                                                                   | 79.6                            | n.a.                    | n.a.                           |
|                                            | 54        | n/a                                                    | IG1 (BFB) 24 months after starting treatment (54)       |                                                                                   | 81.5                            | n.a.                    | n.a.                           |
| Koutsomanis et al. 1994 [22]               | 20        | Study group pre-BFB (20)                               | Study group immediately post-BFB (20)                  | SR: % patients reporting abdominal pain ≥ 1/week                                 | –20                             | n.a.                    | ≥ 0.05                          |
|                                            | 18        | Study group pre-BFB (20)                               | Study group 6 weeks after starting BFB (18)            |                                                                                  | –13.3                           | n.a.                    | ≥ 0.05                          |
|                                            | 20        | Study group pre-BFB (20)                               | Study group 6–12 months after 6-wk-f/u (20)           |                                                                                  | –10                             | n.a.                    | ≥ 0.05                          |
|                                            | 20        | Study group pre-BFB (20)                               | Study group immediately post-BFB (20)                  | Weekly total pain score (daily pain score: 0 = none, 3 = severe)                | –5.5                            | n.a.                    | ≥ 0.05                          |
|                                            | 18        | Study group pre-BFB (20)                               | Study group 6 weeks after starting BFB (18)            |                                                                                  | –8                              | n.a.                    | p < 0.01                      |
|                                            | 20        | Study group pre-BFB (20)                               | Study group 6–12 months after 6-wk-f/u (20)           |                                                                                  | –9                              | n.a.                    | p < 0.01                      |
|                                            | 20        | Study group pre-BFB (20)                               | Study group immediately post-BFB (20)                  | Weekly overall symptom score (daily score: 0 = better, 1 = same, 2 = worse)    | –4                              | n.a.                    | p < 0.01                      |
|                                            | 18        | Study group pre-BFB (20)                               | Study group 6 weeks after starting BFB (18)            |                                                                                  | –4                              | n.a.                    | p < 0.01                      |
|                                            | 20        | Study group pre-BFB (20)                               | Study group 6–12 months after 6-wk-f/u (20)           |                                                                                  | –6                              | n.a.                    | p < 0.01                      |
| Chiotakakou-Faliakou et al. 1998 [23]      | 100       | Study group pre-BFB (100)                              | Study group post-BFB (100)                             | SR: % patients with abdominal pain                                              | –16                             | n.a.                    | p = 0.003                      |
|                                            | 100       | Study group pre-BFB (100)                              | Study group long-term (mean 23.4 months) post-BFB (100) |                                                                                  | –20                             | n.a.                    | p = 0.0004                   |
|                                            | 100       | n/a                                                    | Study group post-BFB (100)                             | SR: % patients stating BFB improved bowel symptoms (a little-a lot)              | 66                              | n.a.                    | n.a.                           |
|                                            | 100       | n/a                                                    | Study group long-term (mean 23.4 months) post-BFB (100) |                                                                                  | 55                              | n.a.                    | n.a.                           |
|                                            | 100       | n/a                                                    | Study group post-BFB (100)                             | SR: % patients reporting sonstipation symptom improvement (a little-a lot)       | 50                              | n.a.                    | n.a.                           |
|                                            | 100       | n/a                                                    | Study group long-term (23.4 months) post-BFB (100) in pat. w constipation |                                                                                  | 57                              | n.a.                    | n.a.                           |
| Study                        | n (total) | Group 1 (n1) | Group 2 (n2) | Outcome measure                      | Mean difference: Group 2 minus Group 1 [CI] | Effect size [strength] | P-value (for difference in means) |
|-----------------------------|-----------|--------------|--------------|--------------------------------------|---------------------------------------------|------------------------|-----------------------------------|
| Battaglia et al. 2004 [24]  | 14        | Subgroup with PF dysynergia pre-BFB (14) | This subgroup 3 + 12 months after BFB (14) | SR: % patients with abdominal pain          | −21.4 n.a. n.a.                                  |                       |                                   |
|                             | 10        | Subgroup with slow transit constipation pre-BFB (10) | This subgroup 3 months post-BFB (10) |                                      | −80 n.a. n.a.                                  |                       |                                   |
|                             | 10        | Subgroup with slow transit constipation pre-BFB (10) | This subgroup 12 months post-BFB (10) |                                      | −20 n.a. n.a.                                  |                       |                                   |
| Wang et al. 2003 [25]       | 50        | Study group pre-BFB (50) | Study group post-BFB (50) | SR: % patients with perianal pain at defecation | −28 n.a. n.a. ≥ 0.05a                             |                       |                                   |
|                             | 50        | Study group pre-BFB (50) | Study group 1-year post-BFB (50) |                                      | −38 n.a. n.a. ≥ 0.05a                             |                       |                                   |
|                             | 8         | n/a          | Study group post-BFB (50) |                                      |                                      |                       |                                   |
|                             | 26        | n/a          | Pat. w PF dysfunction post-BFB (36) |                                      |                                      |                       |                                   |
|                             | 6         | n/a          | Pat. w combined PF dys + slow transit post-BFB (6) |                                      |                                      |                       |                                   |
| Ba-Bai-Ke-Re et al. 2014 [26]| 88       | IG1 (BFB) 1 month post-treatment (44) | IG2 (laxatives) 1 month post-treatment (44) | SR: % of patients with perianal pain at defecation | 36.4 n.a. 0.0006a                             |                       |                                   |
|                             | 88       | IG1 (BFB) 3 months post-treatment (44) | IG2 (laxatives) 3 months post-treatment (44) |                                      | 20.5 n.a. 0.0534a                             |                       |                                   |
|                             | 88       | IG1 (BFB) 6 months post-treatment (44) | IG2 (laxatives) 6 months post-treatment (44) |                                      | 20.5 n.a. 0.0375a                             |                       |                                   |
|                             | 88       | IG1 (BFB) 1 month post-treatment (44) | IG2 (laxatives) 1 month post-treatment (44) | Symptom score: Wexner constipation summary score (0–30 = worst) [62] | −6.00 [−7.41; −4.59] −1.45 [VL] p < 0.001a |                       |                                   |
|                             | 88       | IG1 (BFB) 3 months post-treatment (44) | IG2 (laxatives) 3 months post-treatment (44) |                                      | −5.00 [−6.21;−3.78] −1.40 [VL] p < 0.001a |                       |                                   |
|                             | 88       | IG1 (BFB) 6 months post-treatment (44) | IG2 (laxatives) 6 months post-treatment (44) |                                      | −6.00 [−7.11;−4.89] −1.84 [VL] p < 0.001a |                       |                                   |
| Roy et al. 2000 [27]        | 26       | Pre-BFB in pat. w constipation, attributed to hysterectomy by patient (26) | Post-BFB in patients with constipation, attributed to hysterectomy by patient (26) | SR: % of patients with abdominal pain | −23.1 n.a. n.a.                                  |                       |                                   |
|                             | 26       | Pre-BFB in pat. w constipation, attributed to hysterectomy (26) | Long-term (28 months) post-BFB in patients with constipation, attributed to hysterectomy (26) |                                      | −11.5 n.a. n.a.                                  |                       |                                   |
|                             | 27       | Pre-BFB in pat. w constipation, not attributed to hysterectomy (27) | Post-BFB in pat. w constipation, not attributed to hysterectomy (27) |                                      | −29.6 n.a. n.a.                                  |                       |                                   |
|                             | 27       | Pre-BFB in pat. w constipation, not attributed to hysterectomy (27) | Long-term (28 months) post-BFB in pat. w constipation, not attributed to hysterectomy (27) |                                      | −29.6 n.a. n.a.                                  |                       |                                   |
|                             | 25       | Pre-BFB in pat. w constipation, no history of hysterectomy (25) | Post-BFB in pat. w constipation, no history of hysterectomy (25) |                                      | −28.0 n.a. n.a.                                  |                       |                                   |
|                             | 25       | Pre-BFB in pat. w constipation, no history of hysterectomy (25) | Long-term (28 months) post-BFB in pat. w constipation, no history of hysterectomy (25) |                                      | −36.0 n.a. n.a.                                  |                       |                                   |
|                             | 78       | Pre-BFB in all pat. w constipation (78) | Post-BFB in all pat. w constipation (78) |                                      | −27.0 n.a. n.a.                                  |                       |                                   |
|                             | 78       | Pre-BFB in all pat. w constipation (78) | Long-term (28 months) post-BFB in all pat. w constipation (78) |                                      | −25.6 n.a. n.a.                                  |                       |                                   |
|                             | 78       | n/a          | 28 months post-BFB in all pat. w constipation (78) | SR: % patients reporting constipation symptom improvement | 61.5 n.a. n.a.                                  |                       |                                   |
# Table 5 (Continued)

| Study                        | n (total)       | Group 1 (n1)                  | Group 2 (n2)                  | Outcome measure                                                                 | Mean difference: Group 2 minus Group 1 [CI] | Effect size (strength) | P-value (for difference in means) |
|------------------------------|-----------------|------------------------------|------------------------------|---------------------------------------------------------------------------------|---------------------------------------------|------------------------|----------------------------------|
| Chiarioni et al. 2005 [28]  | 41              | Subgroup with PF dysfunction after 1, 6, 12, 24 months after BFB (52, 50, 49, 45) | Subgroup with slow transit only, after 1, 6, 12, 24 months after BFB (52, 50, 49, 45) | Pain frequency (in favour of subgroup PF dyssynergia) | n.a.                          | n.a.                   | p < 0.05a                        |
| Zhu et al. 2011 [29]        | 36              | Study group pre-BFB (36)     | Study group post-BFB (36)    | SF-36 subscale pain (0–100: best)                                               | 10.3 [–1.31;21.91]                          | 0.48 [S]               | p = 0.001a                       |
|                             | 36              | Study group pre-BFB (36)     | Study group post-BFB (36)    | Symptom score (0–15: 0 = none, 3 = severe for 5 symptoms)                       | −5.77 [−7.29;−4.25]                         | −2.04 [H]              | p < 0.001                        |
| Gilliland et al. 1997b [30] | 178             | Study group post-BFB (178)   | Study group post-BFB (178)   | SR: % patients with ≥3 bowel movements/wk without aid ("complete success")     | 35.0                                        | n.a.                   | n.a.                            |
|                             | 178             | Study group post-BFB (178)   | Study group post-BFB (178)   | SR: % patients with <3 bowel movements/wk with reduced aid ("partial success") | 13.5                                        | n.a.                   | n.a.                            |
|                             | 178             | Study group post-BFB (178)   | Study group post-BFB (178)   | SR: % patients with no improvement ("failed")                                  | 51.1                                        | n.a.                   | n.a.                            |
|                             | 60              | Study group post-BFB, pat. attended 2–4 sessions (60) | Study group post-BFB, pat. attended ≥5 sessions (118) | SR: % patients with ≥3 bowel movements/wk without aid ("complete success")     | 18.0                                        | n.a.                   | n.a.                            |
|                             | 118             | Study group post-BFB, pat. attended ≥5 sessions (118) | Study group post-BFB, pat. attended ≥5 sessions (60) | SR: % patients with ≥3 bowel movements/wk without aid ("complete success")     | 44.0                                        | n.a.                   | n.a.                            |
|                             | 178             | Study group post-BFB, pat. attended ≥5 sessions (118) | Study group post-BFB, pat. completed BFB (52) | SR: % patients with ≥3 bowel movements/wk without aid ("complete success")     | −26.0                                       | n.a.                   | p < 0.001                        |
|                             | 52              | Study group post-BFB, pat. completed BFB (52) | Study group post-BFB, pat. completed BFB (52) | SR: % patients with ≥3 bowel movements/wk without aid ("complete success")     | 63.0                                        | n.a.                   | n.a.                            |
|                             | 126             | Study group post-BFB, pat. not completed BFB (126) | Study group post-BFB, pat. not completed BFB (126) | SR: % patients with ≥3 bowel movements/wk without aid ("complete success")     | (25.0)                                      | n.a.                   | n.a.                            |
|                             | 178             | Study group post-BFB, pat. completed BFB (52) | Study group post-BFB, pat. not completed BFB (126) | SR: % patients with ≥3 bowel movements/wk without aid ("complete success")     | −38.0                                       | n.a.                   | n.a.                            |
| Parker et al. 2019 [31]    | 130             | Study group post-BFB (130)   | Study group post-BFB (130)   | Whole study group post-BFB reporting symptom improvement (±improvement in anorectal manometry profile) | (55.4)                                      | n.a.                   | n.a.                            |
|                             | 53              | Study group post-BFB (53)    | Study group post-BFB (53)    | Subgroup with constipation + dys. defecation post-BFB (53)                       | (45.3)                                      | n.a.                   | n.a.                            |
|                             | 3               | Study group post-BFB (3)     | Study group post-BFB (3)     | Subgroup with rectal pain post-BFB (3)                                          | (0.0)                                       | n.a.                   | n.a.                            |
| **Male chronic pelvic pain syndrome, Urological Chronic Pelvic Pain Syndrome** |                     |                              |                              |                                                                                   |                                             |                        |                                  |
| Clemens et al. 2000 [32]    | 16              | Study group pre-BFB (19)     | Study group 6 months post-BFB (16) | Pain VAS (0–9)                                                                 | −4                                          | n.a.                   | p = 0.001b                       |
|                             | 16              | Study group pre-BFB (19)     | Study group 6 months post-BFB (16) | Symptom score: AUA [59]                                                           | −7.5                                        | n.a.                   | p = 0.001b                       |
| Cornel et al. 2005 [34]     | 31              | Study group re-BFB (33)      | Study group post-BFB (31)    | Symptom score: NIH-CPSI subdomain pain (0–21)                                   | −5.3                                        | n.a.                   | p = 0.001b                       |
|                             | 31              | Study group pre-BFB (33)     | Study group post-BFB (31)    | Symptom score: NIH-CPSI                                                           | −12.2                                       | n.a.                   | p = 0.001b                       |
### Table 5 (Continued)

| Study                        | Group 1 (n1) | Group 2 (n2) | Outcome measure                        | Mean difference: Group 2 minus Group 1 [CI] | Effect size [strength] | P-value for difference in means |
|------------------------------|--------------|--------------|----------------------------------------|---------------------------------------------|------------------------|---------------------------------|
| Yang et al. 2017 [35]        | 22           | 45           | Pelvic pain VAS (0–10)                  | -3.5 [-4.91; -2.09]                         | -1.74 [VL]             | p < 0.001b                      |
|                              | Subgroup w pelvic pain/ | Subgroup w pelvic pain/ | Pain VAS (0–10)                  |                                             |                        |                                 |
|                              | IG1 (BFB + EGS) pretreatment (24) | IG1 (BFB + EGS) 12 weeks post-treatment (22) |                                             |                                             |                        |                                 |
|                              | IG1 (BFB + EGS) 12 weeks post-treatment (22) | IG2 (PEMF) 12 weeks post-treatment (23) |                                             | 0.6 [-1.44; 0.24]                         | -0.34 [S]               | p = 0.084a                      |
|                              | Subgroup w urinary symptoms/ | Subgroup w urinary symptoms/ | NIH-CPSI subdomain pain (0–21) | -8.3 [-10.91; -5.70]                        | -2.23 [T]              | p < 0.001b                      |
|                              | IG1 (BFB + EGS) pretreatment (24) | IG1 (BFB + EGS) 12 weeks post-treatment (22) |                                             |                                             |                        |                                 |
|                              | IG1 (BFB + EGS) 12 weeks post-treatment (22) | IG2 (PEMF) 12 weeks post-treatment (23) |                                             | 0.1 [-1.98; 1.78]                         | -0.03 [VS]              | p = 0.035a                      |
| He et al. 2010 [36]          | 21           | 21           | Pelvic pain VAS (0–10)                  | -1.81 [–19.82;–8.78]                        | -1.81 [VL]             | p < 0.001b                      |
|                              | Study group pre-BFB (21) | Study group 10 weeks post-BFB (21) | Rating treatment success pelvic pain (0: none–10: very successful) | -1 [–8.64;–0.56]                         | -0.80 [M]              | p = 0.004b                      |
|                              | Subgroup w dyspareunia after 3rd treatment (29) | Subgroup w dyspareunia after final treatment (27) | Pelvic pain VAS (0–10)                  | -0.80 [–3.98;2.98]                        | -0.07 [VS]              | p = 0.009b                      |
| Female chronic pelvic pain   | 26           | 27           | Pelvic pain VAS (0–10)                  | -1 n.a.                                    | p = 0.99b               |                                 |
|                              | Subgroup w pelvic pain/ | Subgroup w pelvic pain/ | Rating treatment success pelvic pain (0: none–10: very successful) | 2 n.a.                                     | p = 0.51b               |                                 |
| Schmitt 2017 et al. [37]     | 26           | 27           | Pelvic pain VAS (0–10)                  |                                              |                        |                                 |
|                              | Subgroup w pelvic pain/ | Subgroup w pelvic pain/ | Rating treatment success pelvic pain (0: none–10: very successful) | 3 n.a.                                     | p = 0.20b               |                                 |
|                              | dyspareunia after 3rd treatment (29) | Subgroup w pelvic pain/ |                                             |                                              |                        |                                 |
|                              | Subgroup w pelvic pain/ | Subgroup w pelvic pain/ | Rating treatment success pelvic pain (0: none–10: very successful) | 2 n.a.                                     | p = 0.001b              |                                 |
|                              | dyspareunia after 3rd treatment (29) | Subgroup w pelvic pain/ |                                             |                                              |                        |                                 |
|                              | Subgroup w pelvic pain/ | Subgroup w pelvic pain/ | Rating treatment success pelvic pain (0: none–10: very successful) | 1 n.a.                                     | p = 0.003b              |                                 |
|                              | dyspareunia after 3rd treatment (14) | Subgroup w pelvic pain/ |                                             |                                              |                        |                                 |
|                              | Subgroup w pelvic pain/ | Subgroup w pelvic pain/ | Rating treatment success pelvic pain (0: none–10: very successful) | 6 n.a.                                     | p = 0.001b              |                                 |
|                              | dyspareunia after 3rd treatment (14) | Subgroup w pelvic pain/ |                                             |                                              |                        |                                 |
|                              | Subgroup w pelvic pain/ | Subgroup w pelvic pain/ | Rating treatment success pelvic pain (0: none–10: very successful) | 66.67 n.a.                                  | p = 0.001b              |                                 |
|                              | dyspareunia after 3rd treatment (80) | Subgroup w pelvic pain/ |                                             |                                              |                        |                                 |
|                              | Subgroup w dyspareunia symptoms after 3rd treatment (29) | Subgroup w dyspareunia symptoms after final treatment (27) | Pelvic pain VAS (0–10)                  | -5.7 n.a.                                  | p < 0.001b              |                                 |
| Glazer et al. 1995 [38]      | 33           | 33           | Pelvic pain VAS (0–10)                  | -6 n.a.                                    | p = 0.001b              |                                 |
|                              | Study group pre-BFB (33) | Study group after 6th clinical reevaluation with BFB (33) | SR: % of patients reporting intercourse ≥ 1/month | 66.67 n.a.                                  | p = 0.001b              |                                 |
| McKay et al. 2001 [39]       | 11           | 11           | Pelvic pain VAS (0–10)                  | -6.8 n.a.                                  | n.a.                    |                                 |
|                              | Study group 1 month post-BFB (19) | Study group 6 months post BFB (11) | SR: % of patients reporting intercourse | 88.9 n.a.                                  | n.a.                    |                                 |
| Study | n (total) (group 1, 2) | Group 1 (n1) | Group 2 (n2) | Outcome measure | Mean difference: Group 2 minus Group 1 [CI] | Effect size [strength] | P-value (for difference in means) |
|-------|-----------------------|-------------|-------------|----------------|-----------------------------------------------|------------------------|----------------------------------|
| Genti core-Saulnier et al. 2010 [40] | 11 | IG pre-BFB in pat. with provoked vestibulodynia (11) | IG post-BFB in pat. w provoked vestibulodynia (11) | Pain NRS (0–10) during digital intravaginal assessment of superficial + deep PF | –2.00 [–3.33;–0.67] | –1.56 [VL] | p = 0.007³ |
| | 22 | IG pre-BFB in pat. w provoked vestibulodynia (11) | Healthy CG without intervention (11) | “unpleasantness” NRS (0–10) during manual assessment | –1.63 [–3.03;–0.23] | –1.21 [VL] | p = 0.00009³ |
| | 22 | IG pre-BFB in pat. w provoked vestibulodynia (11) | Healthy CG without intervention (11) | Painful pressure stimulus intensity levels (pressure to induce pain NRS 6/10, g/cm²) | 92.00 [–162.25; 346.25] | 0.37 [S] | p = 0.001³ |
| | 22 | IG post-BFB in pat. w provoked vestibulodynia (11) | Healthy CG without intervention (11) | Symptom score: SSS total score: total of 15 symptoms (1 best –5 worst) (1–5 = very severely) | –8.10 [–14.27; 7.07] | –1.8 [VL] | p = 0.02³ |
| Bendana et al. 2009 [41] | 13 | Study group pre-BFB (52) | Study group 3 months post-BFB (21) | AUA symptom score—total score (0–35) | –7.97 [–12.25;–4.62] | –1.10 [L] | p < 0.001³ |
| | 21 | Study group pre-BFB (52) | Study group 3 months post-BFB (21) | American Urological Association bother score (0–6) | –1.53 [–2.33;–0.87] | –1.13 [L] | p < 0.001³ |
| Phillips et al. 1992 [42] | 10 | IG1 (BF group) pre-BFB (10) | IG1 (BF group) post-BFB (10) | Symptom score: SSS total score: total of 15 symptoms (1 best –5 worst) | –1.30 [–9.20;7.60] | –0.05 [VS] | n.a. |
| | 10 | IG1 (BF group) pre-BFB (10) | IG1 (BF group) 2 months post-BFB (10) | Symptom score: SSS of subdomain cramps, backache, abdominal pain (1–5 = very severely) | –0.6 [–1.47;0.27] | –0.92 [VS] | n.a. |
| Hart et al. 1981 [43] | 5 | IG1: EMG BFB (5) baseline | IG1: EMG BFB (5) posttreatment | Symptom score: SSS total score: total of 15 symptoms (1 best –5 worst) | –7.00 [–11.85;–2.15] | –2.51 [H] | n.a. |
| | 5 | IG1: EMG BFB (5) baseline | IG1: EMG BFB (5) 8 weeks posttreatment | | –9.30 [–12.61;–6.00] | –4.89 [H] | n.a. |
| | 6 | IG2: BFB skin temperature baseline (6) | IG2: BFB skin temperature posttreatment (6) | | –2.00 [–8.86;4.86] | –0.44 [S] | n.a. |
| | 6 | IG2: BFB skin temperature baseline (6) | IG2: BFB skin temperature 8 weeks posttreatment (6) | | –8.10 [–14.25;–1.95] | –2.00 [H] | n.a. |
| Bennink et al. 1982 [44] | 5 | IG1 (relaxation + EMG BFB) pretreatment (5) | IG1 (relaxation + EMG BFB) posttreatment (5) | Symptom score: SSS total of 15 symptoms (1 best –5 worst) | –3.6 [–14.27;7.07] | –0.59 [M] | n.a. |
| | 5 | IG1 (relaxation + EMG BFB) pretreatment (5) | IG1 (relaxation + EMG BFB) posttreatment (5) | SSS of subdomain cramps, backache, abdominal pain (1–5 = very severely) | –1.8 [–4.63;1.43] | –0.92 [L] | n.a. |
| | 5 | IG1 (relaxation + EMG BFB) pretreatment (5) | IG1 (relaxation + EMG BFB) posttreatment (5) | SSS of subdomain cramps only (1–5 = very severely) | –0.6 [–1.47;0.27] | –1.19 [L] | n.a. |
### Table 5 (Continued)

| Study | Group 1 (n1) | Group 2 (n2) | Outcome measure | Mean difference: Group 2 minus Group 1 [CI] | Effect size [strength] | P-value (for difference in means) |
|-------|-------------|-------------|-----------------|---------------------------------------------|------------------------|-----------------------------------|
| Vagedes et al. 2019 [45] | IG1 (BFB group) pre-BFB (20) | IG1 (BFB group) post-BFB (20) | Mean NRS (0–10) pain during menstruation | –0.3 \([-1.2;0.6]\) | –0.2 [VS]\(^a\) | n.a. |
| | IG1 (BFB group) post-BFB (20) | No treatment CG (17) | | 0.9 \([-2.10;0.30]\) | –0.51 [M]\(^b\) | p = 0.211 |
| | IG1 (BFB group) post-BFB (20) | IG2 (rhythmal massage) post-treatment (23) | | –0.6 \([-1.82;0.40]\) | –0.34 [S]\(^b\) | p = 0.361 |
| | IG1 (BFB group) post-BFB (20) | IG1 (BFB group) post-BFB (20) | Maximum NRS (0–10) pain during menstruation | –0.5 \([-1.4;0.3]\) | –0.2 [S]\(^b\) | n.a. |
| | IG1 (BFB group) post-BFB (20) | No-treatment CG (17) | | 0.6 \([-2.18;0.74]\) | –0.4 [S]\(^b\) | p < 0.05 |
| | IG1 (BFB group) post-BFB (20) | IG2 (rhythmal massage) post-treatment (23) | | –0.8 \([-1.94;0.76]\) | –0.23 [S]\(^b\) | p > 0.05 |
| Starr et al. 2013 [46] | Pre-BFB in pat. w urinary symptoms (694) | Post-BFB in pat. w urinary symptoms (n.a.) | % subjective global urinary symptom improvement since initial session (0: none–100%; perfect) | Mean 80–85% improvement\(^b\) | n.a. | n.a. |
| | Pre-BFB in pat. w bowel symptoms (187) | Post-BFB in pat. w bowel symptoms (n.a.) | % subjective global bowel symptom improvement since initial session (0: none–100%; perfect) | Mean 80–85% improvement\(^b\) | n.a. | n.a. |
| | Pre-BFB in pat. w pelvic pain symptoms (368) | Post-BFB in pat. w pelvic pain symptoms (n.a.) | % subjective global pelvic pain symptom improvement since the initial session (0: none–100%; perfect) | Mean 50–90% improve-ment\(^b\) | n.a. | p > 0.05 |
| Lúcio et al. 2014 [47] | IG1 pre BFB, PFM training and sham-electro-stimulation (6) | IG1 post BFB, PFM training and sham electro-stimulation (6) | Symptom score: FSFI subdomain pain | 1.6 | n.a. | p > 0.05\(^b\) |
| | Pre-BFB in pat. w urinary symptoms (694) | Post-BFB in pat. w urinary symptoms (n.a.) | % subjective global urinary symptom improvement since initial session (0: none–100%; perfect) | Mean 80–85% improvement\(^b\) | n.a. | p > 0.05\(^b\) |
| Aalaie et al. 2020 [48] | IG1 (BFB group) pre-treatment (10) | IG1 (BFB group) 3 months post-treatment (9) | Symptom score: FSFI subdomain pain | 0.9 \[0.1;1.6]\(^b\) | η\(^2\) = 0.66 [L]\(^a\) | p = 0.026 |
| | IG1 (BFB group) pre-treatment (10) | IG2 (EGS) 3 months post-treatment (9) | | – | n.a. | η\(^2\) = 0.01 [S]\(^b\) | p = 0.985 |
| | IG1 (BFB group) pre-treatment (10) | IG1 (BFB group) 3 months post-treatment (9) | Symptom score: FSFI total score (2.0–36.0 = best) | 8.9 \[7.0; 10.9]\(^b\) | η\(^2\) = 0.96 [L]\(^a\) | p < 0.001 |
| | IG1 (BFB group) pre-treatment (10) | IG2 (EGS) 3 months post-treatment (9) | | n.a. | η\(^2\) = 0.64 [L]\(^g\) | p = 0.002 |

### Chronic pelvic pain in children

| Study | Group 1 (n1) | Group 2 (n2) | Outcome measure | Mean difference: Group 2 minus Group 1 [CI] | Effect size [strength] | P-value (for difference in means) |
|-------|-------------|-------------|-----------------|---------------------------------------------|------------------------|-----------------------------------|
| Hoebek et al. 2004 [51] | Study group post BFB (21) | SR: % patients reporting complete pain relief | | 80.95 | n.a. | n.a. |
| | Study group long-term f/u (16 months) (21) | 66.67 | n.a. | n.a. |
| Ebiloglu et al. 2016 [52] | Whole study group pre-BFB [136] | Whole study group post BFB (6 months) (136) | SR: % patients with dysuria | –19.85 | n.a. | p = 0.007\(^c\) |
| | Subgroup OBS and dysf. voiding pre-BFB (107) | Post BFB (6 months) in this subgroup (107) | | –20.56 | n.a. | p < 0.001\(^c\) |
| | Subgroup OBS only pre-BFB (23) | Post BFB (6 months) in this subgroup (20) | | –17.24 | n.a. | p < 0.001\(^c\) |
| | Whole study group pre-BFB (136) | Whole study group post BFB (6 months) (136) | Symptom score: LUTDSS | –8.2 | n.a. | p < 0.001\(^c\) |
| Ergin et al. 2016 [53] | IG pat. w dysfunctional voiding pre-BFB in (52) | IG post BFB (6th month) (39) | SR: % patients with dysuria | –83.3 | n.a. | p = 0.063\(^c\) |
| | IG pat. w dysfunctional voiding pre-BFB (52) | IG post BFB (6th month) (39) | Symptom score: NVISSS | –8.3 | n.a. | p = 0.019 |
| Li et al. 2006 [54] | IG pat. w chronic prostatitis pre-BFB (25) | IG post BFB (after –12 weeks) (25) | Symptom score: NIH-CPSI subdomain pain (0–21) | –2 | n.a. | p = 0.001\(^b\) |
| | IG pat. w chronic prostatitis pre-BFB (25) | IG post BFB (after –12 weeks) (25) | Symptom score: NIH-CPSI total score (0–43) | –17 | n.a. | p < 0.001\(^b\) |
quality of life postintervention in eight trials (Table 6). The findings came along with small [29, 35] to huge [26, 36] effect sizes, with 5 studies showing a significant effect for at least some outcomes [26, 29, 35, 36, 45]. A home-based heart rate variability training failed to significantly improve quality of life compared to standard care [45].

**Effect of biofeedback interventions on physiological parameters**

Table 7 presents significant changes in physiological outcome assessment following biofeedback interventions. Biofeedback training could significantly improve at least some manometric values in 9 [16, 20–22, 24–26, 28, 31] out of 10 studies on anorectal dysfunction. In Heah et al. [17] manometric values did not significantly change posttreatment. Six [16, 17, 21, 22, 24, 28] out of 9 studies did not improve resting anal canal pressures. Studies on constipation and dyssynergic defecation found that paradoxical contraction on evacuation [21, 22, 24, 28, 31] and the ability to defecate a balloon [21, 28, 31] could be improved. Patients with dyssynergic defecation could improve more manometric values than patients with slow transit constipation [28]. A landmark trial on anal pain syndrome showed that patients with a tenderness of the levator ani muscle on digital palpation could improve more manometric values than patients without tenderness on the rectal examination [16].

In female chronic pelvic pain, four studies did improve EMGs of the pelvic floor or lower abdomen [38, 39, 44, 52] whereas two (mostly) failed to do so [40, 42].

In urologic phenotypes all [36, 53] or some [52, 54] urodynamic measures could be significantly improved.

**Discussion**

**Quality**

This systematic review included 37 quantitative studies and found tentative evidence that biofeedback-assisted training interventions can improve the primarily evaluated outcomes pain, overall symptoms, and quality of life. Results should be considered with caution due to quality issues of many of the included trials. Only 9 studies had an RCT design, out of which 7 were judged to be of good quality according to PEDro assessment. Many studies were likely underpowered and did not provide a sample size calculation.

Biofeedback is a modality to improve self-efficacy and learning based on operant conditioning [83]. Biofeedback is not used as an intervention on its own but is rather an adjunctive tool to other standard interventions (e.g. pelvic floor exercises, education, lifestyle modification [84]). At times, studies applied biofeedback together with additional physical modalities. Besides, patients were often under medication during the study period for symptom control. Therefore, the single effect of biofeedback intervention is difficult to extract. Biofeedback protocols are difficult to compare between institutions as treatment protocols, biofeedback devices and training amount varied considerably.

Most studies compare improvements within an intervention group which reduces the strength of evidence. Most authors drew their conclusions based on the statistical significance, only two papers [45, 48] reported on effect sizes and confidence intervals of pain and symptom outcomes. Ten studies [21, 26, 29, 35, 36, 40–44] provided data to calculate effect sizes and confidence intervals to evaluate the clinical relevance of the results [85]. The majority of the studies did not perform a post hoc analysis or a correction
| Study | n (total group 1, 2) | Group 1 (n1) | Group 2 (n2) | Outcome measure | MD: group minus group 1 | 95% CI lower bound | 95% CI upper bound | Effect size [strength] | P-value (for difference in means) |
|-------|---------------------|-------------|-------------|-----------------|------------------------|---------------------|---------------------|------------------------|----------------------------------|
| **Constipation, dyssynergic defecation** | | | | | | | | | |
| Ba-Bai-Ke-Re et al. 2014 [26] | 88 | IG1 (BFB) (44) | IG2 (laxatives) (44) | PAC-QoL 1 month post | 12.00 | 10.904 | 13.096 | 3.731 | H | p < 0.001* |
| | 88 | IG1 (BFB) (44) | IG2 (laxatives) (44) | PAC-QoL 3 months post | 14.00 | 13.077 | 14.923 | 5.173 | H | p < 0.001* |
| | 88 | IG1 (BFB) (44) | IG2 (laxatives) (44) | PAC-QoL 6 months post | 16.00 | 15.299 | 16.701 | 7.784 | H | p < 0.001* |
| Zhu et al. 2011 [29] | 36 | Study group pre-BFB (36) | Study group post-BFB (36) | SF-36: physical functioning | 7.30 | −0.679 | 15.279 | 0.494 | S | p = 0.001* |
| | 36 | Pre-BFB (36) | Post-BFB (36) | SF-36: role physical | 10.90 | −1.301 | 21.901 | 0.479 | S | p = 0.001* |
| | 36 | Pre-BFB (36) | Post-BFB (36) | SF-36: bodily pain | 8.00 | −3.932 | 19.932 | 0.362 | S | p = 0.042* |
| | 36 | Pre-BFB (36) | Post-BFB (36) | SF-36: mental health | 11.00 | 0.387 | 38.613 | 0.551 | M | p = 0.001* |
| | 36 | Pre-BFB (36) | Post-BFB (36) | SF-36: social function | 10.90 | −0.701 | 22.510 | 0.507 | M | p = 0.014* |
| | 36 | Pre-BFB (36) | Post-BFB (36) | SF-36: role emotional | 19.50 | 0.387 | 38.613 | 0.551 | M | p = 0.001* |
| Male chronic pelvic pain syndrome, Urological Chronic Pelvic Pain Syndrome | | | | | | | | | |
| Cornel et al. 2005 [34] | 31 | Study group pre-BFB (31) | Study group post-BFB (31) | NIH-CPSI: QoL (0–12 points) | −3.80 | n.a. | n.a. | n.a. | n.a. | p < 0.001b |
| Yang et al. 2017 [35] | 22 | IG1 (BFB + NMES) pretreatment (22) | IG1 12 weeks post-treatment (22) | NIH-CPSI: QoL | −5.20 | −7.523 | −2.870 | −1.564 | VL | p < 0.001a |
| | 45 | BFB + NMES (22) | PEMF (23) | NIH-CPSI: QoL 12 wks post | 1.20 | −0.382 | 2.782 | 0.365 | S | p = 0.012a |
| He et al. 2009 [36] | 21 | Study group pre-BFB (21) | Study group 10 weeks post-BFB (21) | NIH-CPSI: life impact | −6.70 | −8.605 | −4.795 | −2.528 | H | p < 0.05b |
| Female chronic pelvic pain | | | | | | | | | |
| Gentilcore-Saulnier et al. 2010 [40] | 11 | IG (provoked vestibulodynia) pre-BFB (11) | IG post-BFB (11) | Perceived impact on QoL (0 = no to 10 = worst) | −1.55 | −3.367 | 0.267 | −0.882 | L | p = 0.003a |
| Bendana et al. 2009 [41] | 13 | Study group pre-BFB (52) | Study group 3 months post-BFB (13) | VAS (0–10) | −2.56 | n.a. | n.a. | n.a. | n.a. | p < 0.001a |
for multiple testing. Some studies used nonvalidated outcomes to evaluate pain and overall improvement.

The impossibility to fulfill certain quality requirements such as blinding of participants or the administration of placebo treatment, which are standard in pharmacological studies, is inherent to the biofeedback training method and setting.

Given these limitations, the statements that were drawn conducting this review should be understood as tentative evidence and should be considered with caution. Three RCTs of above-average quality with respect to sample size, study design, and reporting [16, 21, 45] are given special attention in the subsequent discussion.

**Efficacy of biofeedback in certain phenotypes and existing recommendations of guidelines**

For anorectal disorders, such as dysynnergic defecation and levator ani syndrome, guidelines exist that state that biofeedback is the preferred treatment for chronic anal pain syndrome (level of evidence IA) [2] and is considered useful in the short-term treatment of levator ani syndrome with dysynnergic defecation (level of evidence IIB) [83]. Biofeedback is recommended for the short-term and long-term treatment of constipation with dysynnergic defecation (level of evidence IA), which is the most common defecation disorder, affecting about 40% of patients with chronic constipation [83]. Biofeedback seems to benefit patients with dysynnergic defecation above other types of constipation [24, 83, 86]. In PF dysynnergia, a landmark trial by Chiarioni et al. [21] found biofeedback to be superior to laxatives (polyethylene glycol), two other RCTs [87, 88] (not considered in this review) also considered it superior to alternative treatments (diazepam), placebo, sham feedback and standard treatment [86]. The pathophysiology of levator ani syndrome seems to be similar to that of dysynnergic defecation, thus similar techniques and protocols have been used [16]. Both EMG and pressure-based biofeedback therapy protocols appear to be efficacious in restoring a normal pattern of defecation, but larger comparative trials are lacking [83]. Surface EMG probes are cheaper, more durable and usually provide a one or two-channel display [83]. Manometric systems are more expensive, have a multiple channel display and can facilitate rectoanal coordination and sensory training because they have a balloon and rectal sensor [83, 86].

In patients with vulvar vestibulitis syndrome (vulvodynia, dyspareunia), preliminary evidence has suggested that altered muscle abnormalities (as shown by altered EMG activity such as elevated resting activity, reduced muscle contraction strength, muscle instability) are present and EMG biofeedback muscle rehabilitation, therefore, is beneficial [1, 38]. According to Mariani, biofeedback should be used as a first-line treatment in moderate to severe vulvar vestibulitis (together with antidepressants and psychological counseling) [89]. Two uncontrolled studies by Glazer et al. and McKay at al. using portable EMG biofeedback devices showed promising results with this indication [38, 39]. Bergeron et al. (not considered in this...

**Table 6** (Continued)

| Study | n (total group 1, 2) | Group 1 (n1) | Group 2 (n2) | Outcome measure | MD: group minus group 1 | 95% CI lower bound | 95% CI upper bound | Effect size strength | P-value (for difference in means) |
|-------|---------------------|--------------|--------------|-----------------|-------------------------|-------------------|-------------------|-------------------|-----------------------------|
| Vagedes et al. 2019 [45] | 20 | IG1 (BFB) pre-BFB (20) | IG1 post-BFB (20) | SF-12: mental score | 4.1<sup>c</sup> | -0.3<sup>c</sup> | 8.4<sup>c</sup> | 0.4<sup>c</sup> | S n.a. |
| | 20 | IG1 (BFB) pre-BFB (20) | IG1 post-BFB (20) | SF-12: physical score | 4.4<sup>c</sup> | 0.4<sup>c</sup> | 8.5<sup>c</sup> | 0.5<sup>c</sup> | S n.a. |
| | 20 | IG1 (BFB) pre-BFB (20) | IG1 post-BFB (20) | SF-12: sum score | 8.7<sup>c</sup> | 3.5<sup>c</sup> | 13.8<sup>c</sup> | 0.6<sup>c</sup> | M n.a. |
| | 37 | IG1 (BFB) post-BFB (20) | CG (usual care) (17) | SF-12: sum score | 6.13<sup>f</sup> | -3.09<sup>f</sup> | 15.35<sup>f</sup> | 0.41<sup>f</sup> | S p<0.05 |
| | 43 | IG1 (BFB) post-BFB (20) | IG2 (massage) post-treatment (23) | SF-12: sum score | -0.57<sup>h</sup> | -0.18<sup>h</sup> | 8.03<sup>h</sup> | -0.04<sup>h</sup> | VS p<0.05 |

**Chronic pelvic pain in children**

| Study | n (total group 1, 2) | Group 1 (n1) | Group 2 (n2) | Outcome measure | MD: group minus group 1 | 95% CI lower bound | 95% CI upper bound | Effect size strength | P-value (for difference in means) |
|-------|---------------------|--------------|--------------|-----------------|-------------------------|-------------------|-------------------|-------------------|-----------------------------|
| Li et al. 2006 [54] | 22 | IG patients with chronic prostatitis post-BFB (25) | IG post-BFB (22) | NIH-CPSI: life impact | 8 | n.a. | n.a. | n.a. | n.a. p<0.001<sup>a</sup> |

Effect size strength: [VS]: very small effect size, [S]: small effect size, [M]: medium effect size, [L]: large effect size, [VL]: very large effect size, [H]: huge effect size; criteria for determining effect sizes for Cohen’s d calculated by the authors (f): [VS]: dz<0.01; [S]: dz<0.20; [M]: dz<0.5; [L]: dz<1.2; [VL]: dz<2.0; [H]: dz≥2.0 according to [61, 63]; criteria for determining effect sizes not calculated by the authors are stated in the respective studies; effect sizes and confidence intervals which were calculated by the review authors are not marked, those effect sizes and confidence intervals that are stated in respective paper are marked with (f).

BFB biofeedback, CG control group, CI confidence interval, IG intervention group, MD mean difference, n.a. not available, NIH-CPSI National Institutes of Health Chronic Prostatitis Symptom Index [66], MMES neurovascular electrical stimulation, PEMF pulsed electromagnetic field therapy, QoL quality of life, SF-12 Short Form-12 [68], SF-36 Short Form 36 [67], UCPS Urological Chronic Pelvic Pain Syndrome, VAS visual analog scale; wk/ks week(s).
Table 7 Secondary outcome: Effect of biofeedback interventions on physiological parameters

| Study                      | Anorectal manometry | Domain, subgroup evaluated | u/u | IG pre-post | IG vs. IG/IG vs. IG/CG | Significant improvement in subdomains, significant difference between IG/IG or IG/CG (p-value) | No significant improvement in subdomains or no significant difference between IG/IG, IG/CG (p-value) |
|----------------------------|---------------------|-----------------------------|-----|-------------|------------------------|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| **Anorectal pain syndrome**|                     |                             |     |             |                        |                                                                                  |                                                                                  |
| Chiarioni et al. 2010 [16] | Anorectal manometry | IG1 BFB group: patients with high likely LAS | Baseline—1 month | x           | –                      | Anal pressure with straining (% relaxing), balloon defecation (% successful), urge threshold (ml), maximum tolerable volume (ml), compliance (mm Hg) (p<0.025) | Resting anal canal pressure (mm Hg), rectoanal inhibitory reflex threshold (ml) (p<0.025) |
|                           |                     |                             | Baseline—3 month | x           | –                      | Anal pressure with straining (% relaxing), balloon defecation (% successful), rectoanal inhibitory reflex threshold (ml), urge threshold (ml), maximum tolerable volume (ml) (p<0.025) | Resting anal canal pressure (mm Hg), compliance (mm Hg) (p<0.025) |
|                           |                     | IG1 BFB group: patients with possible LAS | Baseline—1 month, baseline—3 months | x           | –                      | Anal pressure with straining (% relaxing), balloon defecation (% successful) (p<0.025) | Resting anal canal pressure (mm Hg), rectoanal inhibitory reflex threshold (ml), urge threshold (ml), maximum tolerable volume (ml), compliance (mm Hg) (p<0.025) |
|                           |                     | IG1 BFB group (n=52) vs. IG2 EG5 (n=52) or IG3 massage group (n=53) (in favour of BFB) in patients with high likely LAS | After 1 month, after 3 months | –            | x                      | Anal pressure with straining (% relaxing), balloon defecation (% successful) (p<0.025) | Resting anal canal pressure (mm Hg), rectoanal inhibitory reflex threshold (ml), urge threshold (ml), maximum tolerable volume (ml), compliance (mm Hg) (p<0.025) |
| Heah et al. 1997 [17]     | Anorectal manometry | Study group (n=16)          | Baseline—after treatment | x           | –                      | None (p<0.05²)                                                                 | Anal canal mean resting maximum squeeze pressure (mm Hg), rectum volume first sensation (ml)/maximum tolerable volume (ml)/compliance (ml/mm Hg), perineal descent rest/strain (cm) (p<0.05) |
| Grimaud et al. 1991 [20]  | Anorectal manometry | Study group (n=12)          | Baseline—after treatment | x           | –                      | Anal canal resting pressure (mm Hg), p<0.01 (no significant difference any more compared to healthy controls without BFB intervention) |                                                                                  |
| **Constipation, dyssynergic defecation** |                     |                             |     |             |                        |                                                                                  |                                                                                  |
| Chiarioni et al. 2006 [21] | Anorectal manometry | BFB group (n=54/109)        | Baseline—6 months, baseline—12 months after starting treatment | x           | –                      | Increased anal pressure (α), (paradoxical EMG) increase (α), unable to evacuate balloon (α), anal squeeze pressure (mm Hg), rectoanal inhibitory reflex threshold (ml), urge threshold (ml), maximum tolerable volume (ml), compliance (mm Hg) (p<0.01) | Anal resting pressure (mm Hg) (p<0.01) |
|                           |                     |                             | Baseline—24 months after starting treatment | x           | –                      | Increased anal pressure (α), (paradoxical EMG) increase (α), unable to evacuate balloon (α), anal squeeze pressure (mm Hg), urge threshold (ml), maximum tolerable volume (ml) (p<0.01) | Anal resting pressure (mm Hg), rectoanal inhibitory reflex threshold (ml), compliance (mm Hg) (p<0.01) |
|                           |                     | BFB group vs. laxative group, in favour BFB group (n=109) | 6 and after 12 months after starting treatment | –            | x                      | Increased anal pressure (α), (paradoxical EMG) increase (α), unable to evacuate balloon (α) (p<0.01) | Anal resting pressure (mm Hg), anal squeeze pressure (mm Hg), rectoanal inhibitory reflex threshold (ml), urge threshold (ml), maximum tolerable volume (ml), compliance (mm Hg) |
|                           |                     |                             | 24 months after starting treatment | –            | x                      | No parameter (p<0.01)                                                                 | All parameters (p<0.01) |

Note: The effect of biofeedback interventions on pain, overall symptoms, quality of life and physiological... S35
### Table 7 (Continued)

| Study                        | Domain, subgroup evaluated measure | secondarily | f/u | ITG pre-post | ITG vs. IG/IG | Significant improvement in sub-domains, significant difference between ITG/IG or ITG/CG (p-value) | No significant improvement in sub-domains or no significant difference between ITG/IG or ITG/CG (p-value) |
|------------------------------|------------------------------------|-------------|-----|--------------|---------------|------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Koutsomanolis et al. 1994 [22] | Anorectal manometry                 | Study group (n = 20) | Baseline—after treatment | x  | –            | Paradoxical contraction on evacuation straining (n pre: n = 15/20, n post: n = 0/20, (p: n.a.)) | Anal resting pressure, anal squeeze pressure, anorectal sensation (p: n.a.) |  
| Battaglia et al. 2004 [24]    | Anorectal manometry                 | Patients with PF dyssynergia (n = 14/24) | Baseline—3 months after treatment | x  | –            | Sensation threshold (mm Hg; p = 0.042), paradoxical increase in intra-anal pressure during straining (p: n.a.) | Maximum basal pressure of internal anal sphincter, maximum rectum tolerable volume (p ≥ 0.05) |
| Wang et al. 2003 [25]         | Anorectal manometry                 | Study group (n = 50) | Baseline—after treatment | x  | –            | Anal canal average rest pressure (mm Hg) rectum: initial sense (ml), (p: 0.05) | Anal canal voluntary squeeze (mm Hg), rectum: maximum tolerable volume (ml) and compliance (ml/mm Hg), (p ≥ 0.05) |
| Bai-Bai-Ke-Re et al. 2014 [26] | Anorectal manometry                 | BFB group vs. laxative group, in favor BFB group (n = 88) | Baseline—x | – | x | Anorectal resting pressure, anorectal squeeze pressure (mm Hg) (p ≤ 0.05) | – |
| Chiarioni et al. 2005 [28]    | Gut transit time                    | PF dyssynergia (n = 34) vs. slow transit only (n = 12) | Baseline—1/6/12/24 months after treatment | x  | –            | % of patients with abnormal transit test: baseline: 100%; at all f/u: PF dyssynergia vs. slow-transit-only sign. smaller % of patients with abnormally delayed transit, p < 0.05 | – |
| Balloon defecation test       | Patients with PF dyssynergia (n = 34) | Baseline—after treatment (1, 6, 12, 24 months) | x  | –            | Urge threshold (ml), maximum tolerable pressure (mm Hg), straining rectal pressure (mm Hg), dyssynergia (balloon defecation test) (p ≤ 0.05) | Anal canal resting pressure (ml), rectoanal inhibitory reflex threshold (ml), compliance (mm/Hg100ml), straining rectal pressure (mm Hg) (p ≥ 0.05) |
| Anorectal manometry           | Patients with PF dyssynergia (n = 34) | Baseline—after treatment (1, 6 months) | x  | –            | Urge threshold (ml) (p < 0.05) | Anal canal resting pressure (ml), rectoanal inhibitory reflex threshold (ml), maximum tolerable pressure (mm Hg), compliance (mm/Hg100ml), straining rectal pressure (mm Hg) (p ≥ 0.05) |
| Parker et al. 2019 [31]       | Anorectal manometry                 | Whole study group (constipation, fecal incontinence, rectal pain) (n = 130) | Baseline—after treatment | x  | –            | Resolved dyssynergic manometric pressure profile, balloon expulsion test < 1 min in n = 27/130, (p: n.a.) | – |
|                             | Constipation + dyssycre defecation (n = 33/130) | Baseline—after treatment | x  | –            | Resolved dyssynergic manometric pressure profile, balloon expulsion test < 1 min in n = 13/53, (p: n.a.) | – |
|                             | Constipation without dyssycre defecation (n = 3/130) | Baseline—after treatment | x  | –            | Improvement in anorectal manometry profile (resolved dyssynergic manometric pressure profile, balloon expulsion test < 1 min) in n = 2/3, (p: n.a.) | – |
|                             | Rectal pain (n = 3/130) | Baseline—after treatment | x  | –            | Resolved dyssynergic manometric pressure profile, balloon expulsion test < 1 min in n = 2/3, (p: n.a.) | – |
Table 7 (Continued)

**Male chronic pelvic pain syndrome, Urological Chronic Pelvic Pain Syndrome**

| Study                          | Domain, subgroup                     | t/u        | IG post vs. IG vs. CG | Significant improvement in subdomains, significant difference between IG/IG or IG/CG (p-value) | No significant improvement in subdomains or no significant difference between IG/IG, IG/CG (p-value) |
|-------------------------------|--------------------------------------|------------|-----------------------|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Cornel et al. 2005 [34]       | Levator ani EMG                       | Baseline   | x                     | Mean pelvic muscle tone (μV, p < 0.001)                                                      |                                                                  |
| He et al. 2010 [36]           | Urodynamics (uroflowmetry + EMG)     | Baseline   | x                     | Max. flow rate (ml/s), max. detrusor pressure-storage phase (cmH2O), max. urethra closure pressure (cmH2O), max. urethral pressure (cmH2O) (p < 0.05) |                                                                  |

**Female chronic pelvic pain**

| Study                          | Domain, subgroup                     | t/u        | IG post vs. IG vs. CG | Significant improvement in subdomains, significant difference between IG/IG or IG/CG (p-value) | No significant improvement in subdomains or no significant difference between IG/IG, IG/CG (p-value) |
|-------------------------------|--------------------------------------|------------|-----------------------|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Glazer et al. 1995 [38]       | PF EMG                               | Baseline   | x                     | Muscle contractile strength = mean contraction amplitude (μV), mean relaxation amplitude (μV) (p < 0.0001), SD: measure of the stability of the muscle at rest improved (p: n.a.) |                                                                  |
| McKay et al. 2001 [39]        | PF EMG                               | After 1 month — after 6 months | x                     | Tonic surface EMG resting activity: deep (p < 0.86) or superficial (p < 0.32) PF muscle layer |                                                                  |
| Gentilcore-Saulnier et al. 2010 [40] | PF EMG                           | Baseline, pretreatment | x                     | PF muscle maximum voluntary contractile activity: deep: p = 0.82; superficial: p = 0.50 |                                                                  |
|                              |                                      | Baseline   | x                     | Superficial PFM EMG activity pain responses (μV), (p < 0.0001) Deep PFM layer EMG activity pain response (μV), (p = 0.72) |                                                                  |
|                              |                                      | After treatment | x                     | Sign. greater superficial PFM EMG activity pain responses (μV) in pretreatment IG compared to CG (p = 0.003); sign. higher tonic activity in superficial PFM in pretreatment IG compared to CG (p = 0.04) | No sign. difference pretreatment IG vs. CG for: PFM maximum voluntary contractile activity for deep (p = 0.81) and superficial (p = 0.36) PFM; EMG pain responses of the deep PFM (p = 0.89); deep PFM tonic activity (p = 0.18) |
|                              |                                      | After treatment | x                     | No sign. difference between posttreatment IG and CG: tonic surface EMG resting activity at both superficial (p = 0.82) and deep (p = 0.31) PFM; PFM maximum voluntary contractile activity for deep (p = 0.54) and superficial (p = 0.96) PFM; EMG activity pain response (μV) for deep (p = 0.98) or superficial (p = 0.18) PFM |                                                                  |
|                              |                                      | Baseline — after treatment | x                     | PFM tone (p < 0.001), PFM flexibility (p = 0.01), PFM post-contraction relaxation capacity (p = 0.05), PFM strength (p = 0.04) | Pretreatment PVD group vs. CG: no significant difference in PFM strength (p = 0.54) |
|                              |                                      | Baseline — after treatment | x                     | Pretreatment PVD group vs. CG: PFM tone: sign. higher in PVD group (p = 0.005), PFM flexibility: sign. lower in PVD group (p = 0.01), PFM relaxation: sign. less ability to relax PFM in PVD group (p = 0.02) compared to CG |                                                                  |
|                              |                                      | Baseline — after treatment | x                     | Posttreatment PVD group vs. CG: no sign. difference in PFM tone (p = 0.30), PFM flexibility (p = 1.00), PFM relaxation (p = 0.47), PFM strength (p = 0.12) |                                                                  |

**Digital intravaginal assessment**

| Study                          | Domain, subgroup                     | t/u        | IG post vs. IG vs. CG | Significant improvement in subdomains, significant difference between IG/IG or IG/CG (p-value) | No significant improvement in subdomains or no significant difference between IG/IG, IG/CG (p-value) |
|-------------------------------|--------------------------------------|------------|-----------------------|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
|                              |                                      | Baseline   | x                     | PFM tone (p < 0.001), PFM flexibility (p = 0.01), PFM post-contraction relaxation capacity (p = 0.05), PFM strength (p = 0.04) |                                                                  |
|                              |                                        | IG (n = 11) with provoked vestibulodynia vs. healthy CG (n = 11) | x                     | Pretreatment PVD group vs. CG: PFM tone: sign. higher in PVD group (p = 0.005), PFM flexibility: sign. lower in PVD group (p = 0.01), PFM relaxation: sign. less ability to relax PFM in PVD group (p = 0.02) compared to CG | Pretreatment PVD group vs. CG: no significant difference in PFM strength (p = 0.54) |
|                              |                                      | Baseline   | x                     | Posttreatment PVD group vs. CG: no sign. difference in PFM tone (p = 0.30), PFM flexibility (p = 1.00), PFM relaxation (p = 0.47), PFM strength (p = 0.12) |                                                                  |

| Study                          | Domain, subgroup                     | t/u        | IG post vs. IG vs. CG | Significant improvement in subdomains, significant difference between IG/IG or IG/CG (p-value) | No significant improvement in subdomains or no significant difference between IG/IG, IG/CG (p-value) |
|-------------------------------|--------------------------------------|------------|-----------------------|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Phillips et al. 1992 [42]     | Perivaginal EMG                       | Baseline — after treatment | x                     | Mean EMG scores (seated to void, tending, relaxing, voiding; μV) (p > 0.05) |                                                                  |
review) applied the home-based Glazer protocol in an RCT design. They confirmed that EMG biofeedback as well as cognitive-behavioral therapy and vestibulotony, could improve sexual function and reduce pain (greatest pain reduction in the vestibulectomy group [1, 90, 91]) in the short and long term.

**Pros and cons of biofeedback in pelvic pain conditions and criteria to improve treatment success**

Biofeedback is a safe method, which has not shown any significant adverse effects. This might make biofeedback an attractive treatment option even in indications with a smaller success rate. As biofeedback is a labor-intensive approach [83] and quite time-consuming for both therapist and patient, it is important to preselect those patients who have a high chance of benefiting from the intervention.

The use of biofeedback to treat pelvic pain is based on the idea that these pain conditions may result from, or are associated with, pelvic floor muscle dysfunction. Digital palpation of pelvic floor muscles should be integrated into routine examination to identify myofascial pain as a primary or contributing source of pelvic pain condition [2, 8]. In anorectal pain conditions, tenderness on rectal examination has shown to be a valid criterion of treatment success [16]. Shoskes et al. identified and grouped six clinical phenotypes (urinary, psychosocial, organ-specific, infection, neurologic, tenderness of skeletal muscles) in the UPOINT classification in patients with urologic CPPS [2, 92, 93]. This classification was implemented to help direction therapy according to phenotypes, thereby improving outcomes [93]. Thus, patients with a musculoskeletal phenotype can be selected who most likely benefit from biofeedback interventions.

In patients with constipation, biofeedback therapy seems to benefit especially patients with dyssynergic defecation [21, 24, 28, 83, 86–88].

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**Table 7** (Continued)

| Study | Secondaryly evaluated outcome measure | Domain, subgroup | t/u | IG pre-post | IG vs. IG vs. CG | Significant improvement in subdomains, significant difference between IG/IG or IG/CG (p-value) | No significant improvement in subdomains or no significant difference between IG/IG or IG/CG (p-value) |
|-------|--------------------------------------|-----------------|-----|-------------|-----------------|--------------------------------------------------------------------------------|-----------------------------------------------|
| Bennink et al. 1982 [44] | EMC lower abdomen | IG1 (n=5) vs. IG2 (n=5) | – | – | x | BFB group maintained a significantly lower level of EMG muscle tone (mcV/s) of lower abdomen on 1st day of menstruation compared to massage group (p<0.05) | – |
| Vagedes et al. 2019 [45] | Heart rate variability | BFB group (n=20) | Baseline—after treatment | x | – | SDNNI, RMSSD, LF/HF ratio (p>0.05) | Same values: BFB vs. CG/massage vs. BFB group post treatment: p>0.05 |
| Lúcio et al. 2014 [47] | Intravaginal digital examination | IG1: EMG BFB + PF training + sham NMES (p=6) | Baseline—after treatment | x | – | PF muscle function according to PERFECT scheme [69]: power (0–5 = max. strength), endurance (sec), dynamic endurance (no. of repetitions), fast contractions (no. of repetitions): p<0.05 PF muscle palpation score: PF muscle tone (score: –3 to +3 = very hypertonic), flexibility (score 0–4 = very flexible), ability to relax PF muscles (Score 0–4 = spastic); p>0.05 |

**Chronic pelvic pain in children**

**Ebiloglu et al. 2016 [52]**

| Urodynamics | Study group (n=136) | Baseline—after treatment (6 months) | x | – | No. of patients with positive perineal EMG activity while urinating (p=0.001) | – |

**Urodynamics** | Study group (n=136) | Baseline—after treatment (6 months) | x | – | Mean voided volume (ml, p=0.019), mean maximum flow rate (ml/s, p=0.012) MEAN average flow rate (ml/s, p=0.209), mean voiding time (s, p=0.345), post-void residual volume (ml, p=0.374) |

**Ergin et al. 2016 [53]**

| Urodynamics | Intervention group (n=39) | Baseline—after treatment (6 months) | x | – | Uroflowmetry—post-void residual volume (p<0.001) | – |

**Li et al. 2006 [54]**

| Urodynamics | IG (n=25) | Baseline—after treatment | x | – | Maximum urinary flow rate (ml/s), p=0.001 Postvoid residual urine volume (ml), p=0.08 |

*BFB* biofeedback, *CG* control group (no intervention), *ECS* electroacupuncture stimulation, *EMG* electromyography, *FU* follow-up, *IG* intervention group, *LAS* levator ani syndrome, *LF/HF* ratio ratio of two bands from frequency domain analysis: LF band (0.04–0.15 Hz) indicating sympathetic and parasympathetic activity, HF band (0.15–0.40 Hz) indicating parasympathetic activity, mcV/microvolt, ml/milliliter, ml/minute per second, no. of number(s), PF pelvic floor, *PFM* pelvic floor muscle(s), *RMSSD* root mean square of successive differences; *s* second(s), *SD* standard deviation, *SDNN* standard deviation of normal to normal, vs. versus, wk, wks week(s)
Another criterion of success might be a center's capacities to administer a certain amount of training sessions and the patient's willingness to complete the course of therapy as suggested by the therapist [19]. In patients with chronic constipation and dyssynergic defecation, consensus guidelines on biofeedback therapy [83] recommend 4–6 biofeedback sessions to manage dyssynergic defecation accordingly: 3 sessions [31] achieved a symptom improvement of only 45.3% compared to e.g. 80% achieved by 5 sessions in Chiarioni et al. [21], hence following existing consensus recommendations improves outcome. As biofeedback requires commitment on the patient's part to take responsibility for their own health, the patient's motivation and adequate encouragement to complete the course of therapy through the therapist are other important requirements for the therapeutic success [29, 36]. Cognitive impairment in the older population might lead to slower learning and the need for a higher number of treatment sessions [30]. Medical staff should be capable of demonstrating and explaining the method according to the patient's comprehension and education levels [36]. Similarly, counteracting problems of comprehension by using appropriate explanations and psychological approaches are important in the work with children [54].

The effectiveness of pelvic floor biofeedback training also depends in part on the skills and experience of the biofeedback therapist and the particular techniques that are used to perform the training [28], which is why it is recommended to follow existing consensus guidelines [83].

As the access to biofeedback remains limited in many areas [31] and only a few centers offer biofeedback therapy, home-based self-training program is desirable and is a promising approach in anorectal and gynecologic (vulvar vestibulitis syndrome) disorders [38, 39, 83], at least to continue training after initial training at a center.

With somatoform disorders and related syndromes, the etiology is still not fully understood but evidence supports an interaction of physiological, psychological and interpersonal factors [1]. Therefore, a multimodal treatment strategy can be promoted, using biofeedback, relaxation training and stress management to address physiological and emotional arousal as well as cognitive techniques, psychoeducation and attention training to alter cognitive-perceptual factors, a modification of illness behavior and graded

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Fig. 1 Flow chart of the systematic literature search and the selection according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. UCPPS urological chronic pelvic pain syndrome.
### Table 8: Methodological quality assessment: evaluating all studies included (n = 37): McMaster Critical Review Form (CRF)—Quantitative Studies

| Study design  | Study | Study design | Was the purpose stated clearly? | Was relevant background literature reviewed? | Was the sample size described in detail? | Were the outcome measures described in detail? | Interventions was described in detail? | Contamination was avoided? | Cointervention was avoided? | Results were reported in terms of statistical significance? | Were the analysis method(s) appropriate? | Clinical importance was reported? | Drop-outs were reported? | Conclusions were appropriate given study methods and results? | Total score (sum score) |
|---------------|-------|---------------|----------------------------------|-----------------------------------------------|------------------------------------------|-----------------------------------------------|---------------------------------------|----------------------------|--------------------------|-----------------------------------------------|-----------------------------|-------------------------------|--------------------------|------------------------------------------------|--------------------------|
| Anorectal pain syndrome | Chiarioni et al. 2010 [16] | RCT, 3 arms | Yes | Yes | Yes | Yes | N.add.a | N.add.b | Yes | Yes | No | Yes | Yes | Yes | No | Yes | 10 |
|                    | Heah et al. 1997 [17] | Non-RCT | Yes | Yes | No | No | N.add.a | N.add.b | Yes | N/A | No | Yes | Yes | Yes | No | Yes | 7 |
|                    | Ger et al. 1993 [18] | Non-RCT | Yes | Yes | Yes | No | N.add. | N.add. | Yes | No | N.add. | No | No | Yes | Yes | Yes | 7 |
|                    | Gilliland et al. 1997a [19] | Non-RCT, retrospective | Yes | Yes | Yes | No | N.add. | N.add. | No | N/A | N.add. | Yes | Yes | Yes | Yes | Yes | 8 |
|                    | Grimaud et al. 1991 [20] | Non-RCT | Yes | Yes | Yes | No | N.add.a | N.add.b | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 11 |
| Constipation | Chiarioni et al. 2006 [21] | RCT, 2 arms | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | Yes | 13 |
|                    | Kourtchanis et al. 1994 [22] | Non-RCT | Yes | Yes | No | No | N.add.a | N.add.b | Yes | N/A | No | Yes | Yes | Yes | No | Yes | 7 |
|                    | Chiotakis-Kakou et al. 1998 [23] | Non-RCT, retrospective | Yes | Yes | Yes | No | N.add. | N.add. | Yes | N/A | No | Yes | Yes | Yes | Yes | Yes | 9 |
|                    | Battaglia et al. 2004 [24] | Non-RCT | Yes | Yes | Yes | No | N.add.a | N.add.b | Yes | N/A | No | Yes | Yes | Yes | No | Yes | 8 |
|                    | Wang et al. 2003 [25] | Non-RCT | Yes | Yes | Yes | No | N.add.a | Yes | Yes | Yes | No | Yes | Yes | Yes | No | Yes | 10 |
|                    | Ba-Bai-Ke-Re et al. 2014 [26] | RCT, 2 arms | Yes | Yes | no | Yes | N.add.b | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 11 |
| Study                          | Study design | Was the purpose stated clearly? | Was relevant background literature reviewed? | Was the sample described in detail? | Were the outcome measures valid? | Intervention was described in detail? | Contamination was avoided? | Cointervention was avoided? | Results were reported in terms of statistical significance? | Were the analysis method(s) appropriate? | Clinical importance was reported? | Drop-outs were reported? | Conclusions were appropriate given study methods and results? | Total Score (sum score) |
|-------------------------------|--------------|----------------------------------|----------------------------------------------|-------------------------------------|----------------------------------|--------------------------------------|-------------------------------|-------------------------------|-----------------------------------------------|------------------------------------------|-------------------------------|--------------------------|--------------------------------------|---------------------------|
| Roy 2000 [27]                | Non-RCT, retrospective | Yes                              | Yes                                          | No                                  | N.add.                           | Yes                                   | N/A                           | No                            | Yes                                                          | Yes                                      | Yes                            | No                       | Yes                                                 | 8                         |
| Chianioni et al. 2005 [28]   | Non-RCT      | Yes                              | Yes                                          | No                                  | N.add.                           | Yes                                   | N/A                           | No                            | Yes                                                          | Yes                                      | Yes                            | Yes                      | Yes                                                 | 9                         |
| Zhu et al. 2011 [29]         | Non-RCT      | Yes                              | Yes                                          | Yes                                 | Yes                              | Yes                                   | N/A                           | No                            | Yes                                                          | Yes                                      | Yes                            | Yes                      | No                                                   | 11                        |
| Gilliland et al. 1997b [30]  | Non-RCT, retrospective | Yes                              | Yes                                          | No                                  | N.add.                           | N.add.                               | No                            | N/A                           | No                            | Yes                                      | Yes                            | Yes                      | Yes                     | No                                                   | 7                         |
| Parker et al. 2019 [31]      | Non-RCT, retrospective | Yes                              | Yes                                          | No                                  | No                               | N.add.                               | No                            | No                            | N/A                           | N.add.                                   | No                            | Yes                      | Yes                     | Yes                                                   | 5                         |
| Male chronic pelvic pain syndrome, Urological Pelvic Pain Syndrome |                           |                                   |                                              |                                     |                                  |                                      |                               |                               |                                               |                           |                               |                      |                                                      |                      |
| Clemens et al. 2000 [32]     | Non-RCT      | Yes                              | Yes                                          | No                                  | No                               | N.add.                               | N.add.                         | Yes                           | Yes                                                          | Yes                                      | Yes                            | Yes                      | Yes                                                 | 8                         |
| Cornel et al. 2005 [34]      | Non-RCT      | Yes                              | Yes                                          | No                                  | Yes                              | Yes                                   | N/A                           | N.add.                        | Yes                                                          | Yes                                      | Yes                            | Yes                      | Yes                                                 | 11                        |
| Yang et al. 2017 [35]        | Non-RCT, retrospective | Yes                              | Yes                                          | No                                  | N.add.                           | Yes                                   | Yes                           | Yes                           | Yes                                                          | Yes                                      | Yes                            | Yes                      | Yes                                                 | 12                        |
| He et al. 2010 [36]          | Non-RCT, retrospective | Yes                              | No                                           | No                                  | N.add.                           | N.add.                               | No                            | N/A                           | Yes                                                          | Yes                                      | Yes                            | Yes                      | Yes                                                   | 6                         |
| Study                          | Study design          | Was the purpose stated clearly? | Was relevant background literature reviewed? | Was the sample described in detail? | Was the outcome measures valid? | Intervention was described in detail? | Contamination was avoided? | Cointervention was avoided? | Results were reported in terms of statistical significance? | Were the analysis method(s) appropriate? | Clinical importance was reported? | Drop-outs were reported? | Conclusions were appropriate given study methods and results? | Total score (sum score) |
|-------------------------------|-----------------------|---------------------------------|---------------------------------------------|-------------------------------------|---------------------------------|---------------------------------------|-----------------------------|-----------------------------|---------------------------------------------------------------|-----------------------------------------------|---------------------------------|--------------------------|-------------------------------------------------------------|------------------|
| Schmitt et al. 2017 [37]     | Non-RCT               | Yes                             | Yes                                         | No                                  | No                              | N.add.a                               | Yes                         | Yes                        | N/A                                                                          | N.add.                                                  | Yes                             | Yes                      | Yes                                                         | 9                |
| Glazer et al. 1995 [38]      | Non-RCT               | No                              | Yes                                         | Yes                                 | No                              | N.add.a                               | N.add.                     | Yes                        | N/A                                                                          | No                                                                      | Yes                             | Yes                      | Yes                                                         | 7                |
| McKay et al. 2001 [39]       | Non-RCT               | Yes                             | Yes                                         | Yes                                 | No                              | N.add.a                               | Yes                         | N/A                        | Yes                                                                          | Yes                                                                      | Yes                             | Yes                      | Yes                                                         | 9                |
| Gentilcore-Saulnier et al. 2010 [40] | Non-RCT               | Yes                             | Yes                                         | Yes                                 | Yes                             | Yes                                   | Yes                         | Yes                        | N/A                                                                          | Yes                                                                      | Yes                             | Yes                      | Yes                                                         | 12               |
| Bendana et al. 2009 [41]     | Non-RCT, retrospective | Yes                             | Yes                                         | Yes                                 | No                              | N.add.a                               | No                          | Yes                        | N/A                                                                          | N.add.                                                  | Yes                             | Yes                      | Yes                                                         | 9                |
| Phillips 1992 [42]           | RCT                   | Yes                             | Yes                                         | Yes                                 | No                              | N.add.a                               | N.add.                     | Yes                        | No                                                                           | N.add.                                                  | Yes                             | Yes                      | No                                                         | 8                |
| Hart et al. 1981 [43]        | Non-RCT, 2 arms       | Yes                             | Yes                                         | Yes                                 | No                              | N.add.                               | N.add.                     | Yes                        | Yes                                                                          | N.add.                                                  | Yes                             | No                       | Yes                                                         | 8                |
| Bennink 1982 [44]            | RCT, 3 arms           | Yes                             | Yes                                         | No                                  | No                              | N.add.                               | N.add.                     | Yes                        | Yes                                                                          | Yes                                                                      | Yes                             | Yes                      | Yes                                                         | 9                |
| Vagedes et al. 2019 [45]     | RCT, 3 arm            | Yes                             | Yes                                         | Yes                                 | Yes                             | N.add.a                               | Yes                        | Yes                        | N.add.                                                                        | Yes                                                                      | Yes                             | Yes                      | Yes                                                         | 12               |
| Starr et al. 2013 [46]       | Non-RCT, retrospective| Yes                             | Yes                                         | Yes                                 | Yes                             | N.add.a                               | No                          | Yes                        | N/A                                                                          | Yes                                                                      | Yes                             | Yes                      | Yes                                                         | 10               |
| Lúcio et al. 2014 [47]       | RCT, 3 arm            | Yes                             | Yes                                         | Yes                                 | No                              | N.add.a                               | Yes                        | Yes                        | N.add.                                                                        | Yes                                                                      | Yes                             | Yes                      | Yes                                                         | 11               |
| Aalaie et al. 2020 [48]      | RCT, 2 arm            | Yes                             | Yes                                         | Yes                                 | Yes                             | N.add.a                               | Yes                        | Yes                        | N.add.                                                                        | Yes                                                                      | Yes                             | Yes                      | Yes                                                         | 12               |
| Study design | Was the purpose stated clearly? | Was relevant background literature reviewed? | Was the sample described in detail? | Was the outcome measures reliable? | Intervention was described in detail? | Contamination was avoided? | Cointervention was avoided? | Results were reported in terms of statistical significance? | Were the analysis method(s) appropriate? | Clinical importance was reported? | Dropouts were reported? | Conclusions were appropriate given study methods and results? | Total score (sum score) |
|----------------|---------------------------------|---------------------------------------------|-----------------------------------|-----------------------------------|--------------------------------------|-----------------------------|-----------------------------|--------------------------------------|----------------------------------|-------------------------------|-----------------------------|----------------------------------|-----------------------------|
| Chronic pelvic pain in children in children |
| Hoebbeke et al. 2004 [51] | Non-RCT | Yes | Yes | Yes | No | N.add. | N.add. | Yes | N/A | No | No | N.add. | Yes | No | No | 5 |
| Ebiloglu et al. 2016 [52] | Non-RCT, retrospective | Yes | Yes | Yes | Yes | N.add. | N.add. | Yes | N/A | N.add. | Yes | Yes | Yes | Yes | No | Yes | 9 |
| Ergin et al. 2016 [53] | Non-RCT | Yes | Yes | Yes | No | N.add. | Yes | No | N/A | N.add. | Yes | Yes | Yes | Yes | Yes | Yes | 9 |
| Li et al. 2006 [54] | Non-RCT | Yes | Yes | Yes | No | N.add. | Yes | No | N/A | Yes | Yes | Yes | Yes | Yes | Yes | Yes | 10 |
| Musculoskeletal, low back pain, myofascial pain |
| Kent et al. 2015 [55] | RCT, 2 arms | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | Yes | 13 |

McMaster CRF: 15 items; total score = 14; study design item does not contribute to total score; codes: yes = 1, no = 0, N/A (not applicable) = 0, N.add not addressed (no information provided in the study) = 0 [5]; 4not addressed in respective paper, but at least one main outcome tool was judged to be valid/reliable by review authors (described in the literature). Total score: higher scores indicate higher methodological quality, resulting in a possible total score of 14 points.
### Table 9 Methodological quality assessment, evaluating the included randomized controlled trials (n = 9): Physiotherapy Evidence Database (PEDro) scale [81]

| Criteria | Eligibility criteria and source | Random allocation | Concealed allocation | Baseline comparability | Blinding of subjects | Blinding of therapists | Adequate follow-up (>85%) | Intention-to-treat analysis | Between-group statistical comparisons | Reporting of point measures and measures of variability | Total score | Quality |
|----------|--------------------------------|-------------------|----------------------|------------------------|----------------------|-----------------------|-------------------------|-----------------------------|---------------------------------|-----------------------------------------|-----------|---------|
| Chiarioni et al. 2010 [16] | Yes | Yes | Yes | Yes | No | No | Yes | Yes | Yes | Yes | Yes | 8 | Good |
| Chiarioni et al. 2006 [21] | Yes | Yes | Yes | Yes | No | No | Yes | No | No | Yes | Yes | 6 | Good |
| Ba-Bai-Kere et al. 2014 [26] | Yes | Yes | No | Yes | No | No | No | Yes | Yes | Yes | Yes | 5 | Fair |
| Phillips et al. 1992 [42] | Yes | Yes | No | Yes | No | No | No | Yes | Yes | Yes | Yes | 7 | Good |
| Bennink et al. 1982 [44] | Yes | Yes | No | Yes | No | No | Yes | Yes | Yes | Yes | Yes | 6 | Good |
| Vagedes et al. 2019 [45] | Yes | Yes | Yes | Yes | No | No | No | Yes | Yes | Yes | Yes | 6 | Good |
| Lúcio et al. 2014 [47] | No | Yes | No | Yes | Yes | No | Yes | No | No | Yes | Yes | 6 | Good |
| Astale et al. 2020 [48] | Yes | Yes | Yes | Yes | No | No | No | Yes | Yes | Yes | Yes | 7 | Good |
| Kent et al. 2015 [53] | Yes | Yes | No | Yes | No | No | No | Yes | Yes | Yes | Yes | 5 | Fair |

PEDro scale: 11 items; total score: 10; eligibility criteria item does not contribute to total score; codes: yes = 1, no = 0; quality score: < 4 = poor quality, 4–5 = fair quality, 6–8 = good quality, 9–10 = excellent quality [80]

Activity [1]. Multidisciplinary management, which is a common approach to many chronic conditions, is still not commonly available in gynecology because of cost factors and limited availability of interested specialists [7]. Yet multidisciplinary, multimodal and phenotype-oriented approaches have been increasingly proposed to deal with gynecologic phenotypes, such as provoked vestibulodynia and myofascial pain as well as with other chronic pelvic pain conditions such as bladder or prostate pain syndrome [2, 8, 90, 93].

Hence, biofeedback is not a complementary or alternative but an additive method for both diagnostic and therapeutic purposes. It should be used in addition to standard care, based on a state of the art concept, if the physician in charge gives the indication.

**Limitations of the present review**

The authors decided to include any quantitative study type of primary research to present a comprehensive overview of the current literature. This reduces the methodological quality of the trials and thereby the significance of the results.

The search term “pelvic pain” is wide-ranging, yet there are many terms used in literature to describe pain syndromes which are perceived in a certain organ [94] and specific pathologies that cause pelvic pain. Therefore, our pragmatic and generalized search strategy carries the risk of missing relevant articles. Studies evaluating biofeedback on constipated patients were included, yet constipation was not the primary focus of this paper as the pain component is not paramount; however, this phenotype has been researched in depth, and our search term did not reveal all relevant studies available in the literature. As with the phenotype of dyspareunia, the reader is referred to the respective relevant literature [14, 83, 86, 90].

Due to language restrictions, studies that would have otherwise fulfilled the inclusion criteria could not be included.

**Conclusion**

Several landmark studies demonstrated the efficacy of biofeedback for anorectal disorders. For other phenotypes of chronic pelvic pain, there is tentative evidence that biofeedback-assisted training interventions can improve the outcomes on pain, overall symptoms, and quality of life. Clinical improvements came along with improvements in certain physiological parameters in several studies. Many trials were characterized by methodological limitations, such as a very small sample size, nonvalidated outcomes and...
a lack of control group. The preliminary positive findings should be investigated further in robust and well-designed randomized controlled trials. Certain factors have been identified that might be relevant for improving biofeedback treatment success.

**Implications for future research**

Future studies should aim to:

- conduct a systematic literature review using MeSH terms that more thoroughly evaluate the effect of biofeedback therapy in a certain phenotype (e.g. anorectal disorders, urological chronic pelvic pain syndrome, bladder pain syndrome, gynecologic pelvic pain conditions);
- list the term “pelvic pain” in the keywords of studies on certain pelvic pain subtypes so that these trials are detected by a literature search on the umbrella term (as chronic pelvic pain comprises many phenotypes);
- improve the quality of future studies, e.g. by choosing an RCT study design that is based on a sample size calculation, performing a post hoc analysis or a correction for multiple testing;
- report on the effect size and an estimate of their precision such as the confidence interval to describe the clinical relevance of results;
- conduct future trials with more homogeneous outcome assessment (to allow future meta-analysis). Ideally, validated questionnaires or pain scales should be used to measure outcome. For stating success rates, an international consensus on the graduation of these rating scales would be beneficial to standardize outcome and improve comparability between study results;
- continue to evaluate the optimum type and extent of biofeedback interventions for the certain phenotypes;
- evaluate changes in quality of life and psychological parameters, such as anxiety and depression (as psychological disorders are common comorbidities in patients with chronic pain conditions).

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