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REVIEW ARTICLE

Biofeedback for the treatment of female pelvic floor muscle dysfunction: a systematic review and meta-analysis

Fátima Faní Fitz · Ana Paula Magalhães Resende · Liliana Stüpp · Marair Gracio Ferreira Sartori · Manoel João Batista Castello Girão · Rodrigo Aquino Castro

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Abstract Biofeedback (BF) has been widely used in the treatment of pelvic floor dysfunctions, mainly by promoting patient learning about muscle contraction with no side effects. However, its effectiveness remains poorly understood with some studies suggesting that BF offers no advantage over the isolated pelvic floor muscle training (PFMT). The main objective of this study was to systematically review available randomized controlled trials assessing the effectiveness of BF in female pelvic floor dysfunction treatment. Trials were electronically searched and rated for quality by use of the PEDro scale (values of 0–10). Randomized controlled trials assessing the training of pelvic floor muscle (PFM) using BF in women with PFM dysfunction were selected. Outcomes were converted to a scale ranging from 0 to 100. Trials were pooled with software used to prepare and update Cochrane reviews. Results are presented as weighted mean differences with 95 % confidence intervals (CI). Twenty-two trials with 1,469 patients that analyzed BF in the treatment of urinary, anorectal, and/or sexual dysfunctions were included. PFMT alone led to a superior but not significant difference in the function of PFM when compared to PFMT with BF, by using vaginal measurement in the short and intermediate term: 9.89 (95 % CI −5.05 to 24.83) and 15.03 (95 % CI −9.71 to 39.78), respectively. We found a few and nonhomogeneous studies addressing anorectal and sexual function, which do not provide the cure rate calculations. Limitations of this review are the low quality and heterogeneity of the studies, involving the usage of distinct protocols of interventions, and various and different outcome measures. The results of this systematic review suggest that PFMT with BF is not more effective than other conservative treatments for female PFM dysfunction.

Keywords Biofeedback · Pelvic floor muscle · Urinary incontinence · Fecal incontinence · Sexual dysfunction

Abbreviations

BF	Biofeedback
PFMT	Pelvic floor muscle training
PFM	Pelvic floor muscle

Introduction

Pelvic floor dysfunction is a general term that describes a wide variety of functional clinical problems, usually associated with abnormalities in the pelvic floor compartments. The anterior compartment has been implicated in sexual and urinary function, with urinary incontinence, pelvic organ prolapse, and sexual dysfunction the most common related symptoms. The posterior compartment is related to colorectal function, and the most common symptom seen in dysfunction of this compartment is fecal incontinence [1].

Physical therapy works to prevent and treat pelvic floor disorders. Its aim is to reduce the impact of pelvic floor dysfunction by improving the function and strength of the pelvic floor muscles (PFMs) [2]. Biofeedback (BF) is one physical therapy adjunct that might be useful in the treatment of pelvic floor dysfunction. It is a technique in which information about a normal physiological process is presented to the patient via subconscious methods and/or via the therapist offering a visual, auditory, or tactile cue [3].

F. F. Fitz (✉) · A. P. M. Resende · L. Stüpp · M. G. F. Sartori · M. J. B. C. Girão · R. A. Castro
Department of Gynecology, Federal University of São Paulo, São Paulo, Brazil
e-mail: fanifitz@yahoo.com.br

This method has been used to teach patients awareness of their muscle functioning in order to improve and motivate the patient's efforts during training [4–6].

Arnold Kegel used to base his training protocol on instructing patients about the correct way to contract their PFMs by using vaginal palpation and clinical observation. In his work, he also used the vaginal squeeze pressure measurement as BF during PFM exercises [7]. Since that time, a variety of other BF instruments have been used during PFM training (PFMT). However, some studies have shown that there is no advantage in using PFMT with BF in this manner; as a result, the effectiveness of this adjunctive modality remains poorly understood.

Therefore, the purpose of the present study was to systematically review randomized controlled trials that evaluated the additional effects of PFMT with BF when compared with other conservative treatments that do not include BF in the treatment of female pelvic floor dysfunction at short, intermediate, and long-term follow-up evaluations. The outcomes of interest were symptoms, quality of life, and function of the PFMs.

Methods

Data sources and searches

A computerized electronic advanced search was performed to identify relevant studies using specific databases. The search was conducted on MEDLINE (1966 to March 2011), LILACS (1993 to March 2011), PubMed (1974 to March 2011), and PEDro (1985 to March 2011). Terms for BF and PFM dysfunction were included in the search by use of MeSH (Medical Subject Headings of the National Library of Medicine) and keywords related to the domains of randomized controlled trials; BF and PFM dysfunction were used for each database (Appendix). We included only the studies written in English. One reviewer screened the search results for potentially eligible studies, while the other two reviewers independently reviewed the screened articles for eligibility. A third independent reviewer resolved any disagreement concerning the inclusion of trials.

Study selection

Studies were eligible for inclusion if they were randomized controlled trials comparing PFMT with BF to placebo or no treatment, PFMT without BF, electrical stimulation, or another conservative treatment for women with PFM dysfunction. Trials were considered to have evaluated PFMT with BF when the treatment included the following features:

- PFMT with BF was used alone, without involving other techniques, and at least one of the groups received the treatment
- PFMT with BF was used for treatment of urinary incontinence, stress urinary incontinence, overactive bladder, fecal incontinence, anal incontinence, constipation, or sexual dysfunction

Trials were included when one of the following outcome measures were reported: symptoms, quality of life or strength, and/or PFM function.

For this review, BF was regarded as a form of intervention involving visual or auditory feedback from an activity using a tool (surface electromyography or manometry). Several questions were proposed:

- What is the effect of treatment with PFMT with BF on the symptoms of women with PFM disorders?
- What is the effect of treatment with PFMT with BF on PFM function in women with disorders of the PFM?
- What is the effect of treatment with PFMT with BF on quality of life in women with PFM disorders?
- Does PFMT with BF yield better results when compared with conservative treatments that do not include BF?

Data synthesis and analyses

The methodological quality of the trials was assessed using the PEDro scale (values of 0–10), with scores extracted from the PEDro database [8]. The assessment of the quality of trials in the PEDro database was performed by two independent raters, and disagreements were resolved by a third rater. Methodological quality was not an inclusion criterion. Mean scores, standard deviations, and sample sizes were extracted from the studies. When this information was not provided in the trial, the values were calculated or estimated by use of methods recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* [9]. Means, standard deviations, and sample sizes were extracted for short-term (less than 3 months after randomization), intermediate-term (at least 3 months but less than 6 months after randomization), and long-term (12 months or more after randomization) follow-up evaluations. When more than one outcome measure was used to assess symptoms, quality of life, perceived effect, strength, and/or PFM function, the outcome measure described as the primary outcome measure for the trial was included in this review.

Results were pooled when trials were considered sufficiently homogeneous with respect to participant characteristics, interventions, and outcomes. I^2 was calculated using RevMan 5.1 [10] to assess statistical heterogeneity. I^2 describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance). A value of greater than 50 % may be considered to

be substantial heterogeneity [9]. When trials were statistically homogeneous ($I^2 \leq 50$ %), pooled effects (weighted mean differences) were calculated by use of a fixed effects model. When trials were statistically heterogeneous ($I^2 \geq 50$ %), estimates of pooled effects (weighted mean differences) were obtained by use of a random effects model [9].

Results

Study selection

The first electronic database search resulted in a total of 404 articles after the removal of duplicates. As shown in Fig. 1, 67

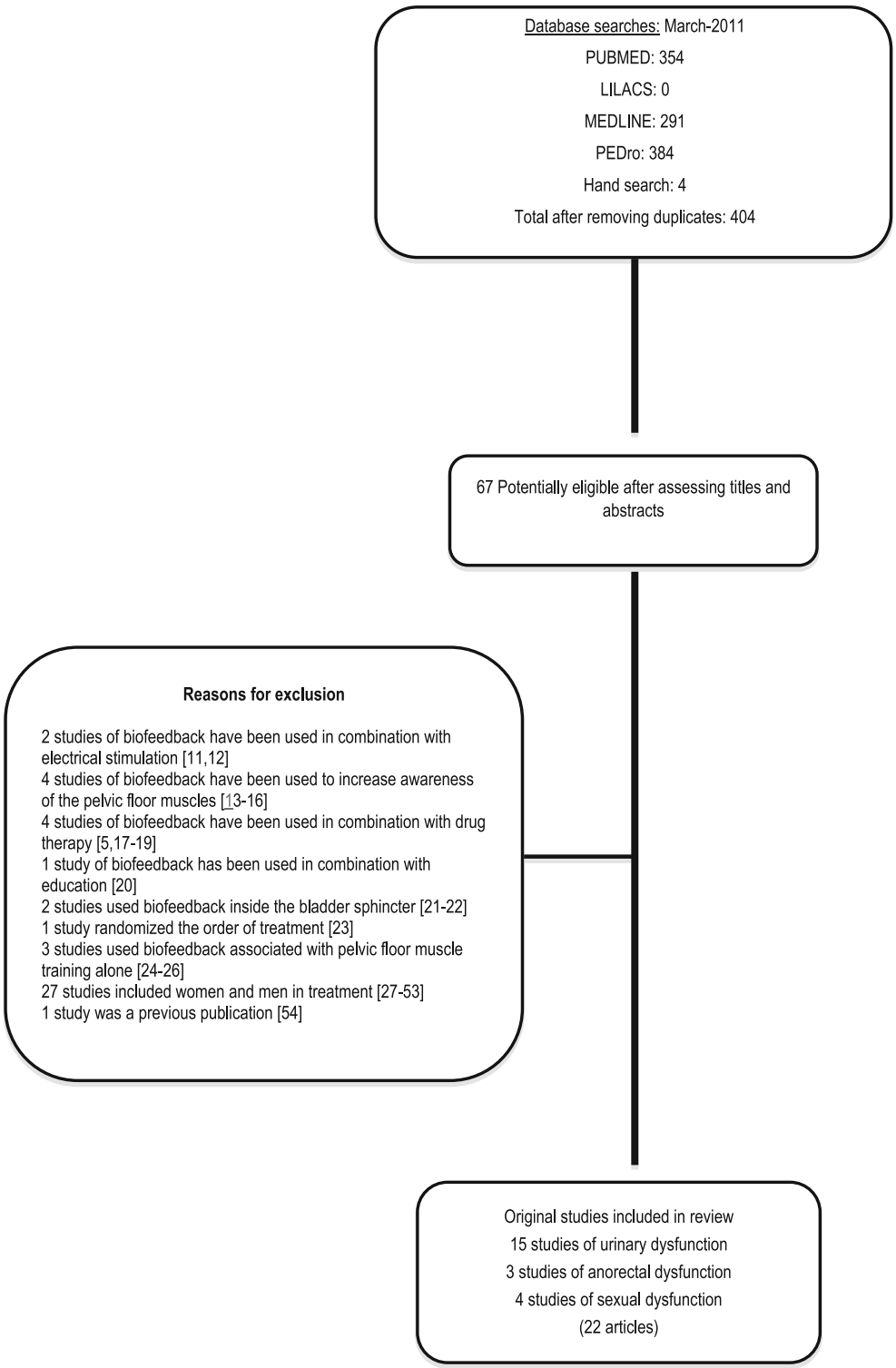

Fig. 1 Flowchart of the systematic review inclusion and exclusion criteria

articles were selected as potentially eligible on the basis of their title and abstract, and 45 were excluded from analysis [5, 11–54]. A total of 22 studies were included in this review. Of these, 15 studies addressed urinary dysfunction, 3 studies related to anorectal dysfunction, and 4 evaluated sexual dysfunction (Fig. 1). Among the studies that addressed urinary dysfunction, only five were included in the meta-analysis. Regarding studies that addressed anorectal and sexual dysfunction, no match was found; therefore, we could not include any of the studies in this meta-analysis.

Methodological quality

The methodological quality assessment by the PEDro scale revealed a median score of 5 (range 2–8) for studies evaluating BF in urinary dysfunction (Table 1). Random allocation was included in all trials. Concealed allocation was included in two trials [55, 56]. Comparability at baseline was not included in four trials [57–59]. Blind subjects and blinding of the therapist were not included in any of the trials. Blind assessors were included in four trials [55, 56, 60, 61]. Adequate follow-up was not included in four trials [62–65]. Intention-to-treat analyses were not included in three trials [60, 63, 66]. Between-group comparisons were not included in three trials [57, 63, 66]. Point estimates and variability were not included in one study [63].

With regard to studies that used BF to treat anorectal dysfunction, the PEDro scale revealed a median score of 5 (range 4–7) (Table 2). Random allocation, comparability at baseline, point estimates, variability, and between-group comparisons were included in all studies [70–72]. Concealed allocation was included in only one study [71], and blind assessors and adequate follow-up were included in two trials [70, 71]. Blind subjects, blinding of the therapist, and intention-to-treat analyses were not included in any of the trials.

With respect to studies which used BF to treat sexual dysfunction, the PEDro scale revealed a median score of 5 (range 4–7) (Table 3). In four trials that met the eligibility criterion, random allocation, between-group comparisons, and point estimates were included [73–76]. Concealed allocation and blind subjects were not included in any of these trials. Comparability at baseline was included in three trials [73–75]. Blinding of the therapist and blinding of the assessors were included in two trials [73, 75]. Adequate follow-up was included in one trial [76]. Intention-to-treat analysis was included in two trials [73, 76].

Study characteristics

BF in the treatment of urinary dysfunction

Fifteen randomized controlled trials included in this review evaluated BF in the treatment of urinary incontinence (Table 4). Fourteen studies evaluated the training of the PFMs with BF for the treatment of stress urinary incontinence and/or mixed urinary incontinence [55–60, 62–69]. One study evaluated PFM training with BF as treatment for overactive bladder [61].

PFMT with BF versus PFMT alone

Twelve trials with a total of 553 patients compared PFMT with BF and PFMT alone [55–58, 60, 61, 63, 65–69]. The

Table 1 PEDro scale for the assessment of the methodological quality assessment of the included studies—urinary dysfunction

Study	E[a]	1	2	3	4	5	6	7	8	9	10	Total score
Shepherd et al. 1983 [66]	−	+	−	+	−	−	−	+	−	−	+	4
Ferguson et al. 1990 [57]	+	+	−	−	−	−	−	+	+	−	+	4
Burns et al. 1993 [67]	+	+	−	+	−	−	−	+	+	+	+	6
Berghmans et al. 1996 [55]	+	+	+	+	−	−	+	+	+	+	+	8
Wyman et al. 1998 [62]	+	+	−	+	−	−	−	−	+	+	+	5
Laycock et al. 2001 [63]	+	+	−	+	−	−	−	−	−	−	−	2
Pages et al. 2001 [58]	+	+	−	−	−	−	−	+	+	+	+	5
Dougherty et al. 2002 [64]	+	+	−	−	−	−	−	−	+	+	+	4
Mørkved et al. 2002 [56]	+	+	+	+	−	−	+	+	+	+	+	8
Aukee et al. 2002 [68]	+	+	−	+	−	−	−	+	+	+	+	6
Aksac et al. 2003 [65]	+	+	−	+	−	−	−	−	+	+	+	5
Wang et al, 2004 [61]	+	+	−	+	−	−	+	+	+	+	+	7
Aukee et al. 2004 [69]	+	+	−	+	−	−	−	+	+	+	+	6
Demirtürk et al. 2008 [59]	+	+	−	−	−	−	−	+	+	+	+	5
Schmidt et al. 2009 [60]	+	+	−	+	−	−	+	+	−	+	+	6

E eligibility, *1* random allocation, *2* concealed allocation, *3* baseline comparability, *4* blind subjects, *5* blind therapists, *6* blind assessors, *7* adequate follow-up, *8* intention-to-treat analysis, *9* between-group comparisons, *10* point estimates and variability, + criterion is clearly satisfied, − criterion is not satisfied

[a] Eligibility criteria item does not contribute to total score

Table 2 PEDro scale for assessment of the methodological quality assessment of the included studies—anorectal dysfunction

Study	E[a]	1	2	3	4	5	6	7	8	9	10	Total score
Fynes et al. 1999 [70]	+	+	−	+	−	−	+	+	−	+	+	6
Mahony et al. 2004 [71]	+	+	+	+	−	−	+	+	−	+	+	7
Naimy et al. 2007 [72]	+	+	−	+	−	−	−	−	−	+	+	4

E eligibility, *1* random allocation, *2* concealed allocation, *3* baseline comparability, *4* blind subjects, *5* blind therapists, *6* blind assessors, *7* adequate follow-up, *8* intention-to-treat analysis, *9* between-group comparisons, *10* point estimates and variability, + criterion is clearly satisfied, − criterion is not satisfied

[a] Eligibility criteria item does not contribute to total score

methodological quality of these trials ranged from 2 to 8. For the five studies [56–58, 60, 65] in which the function of the PFM was evaluated by the vaginal pressure measurement, the results revealed no statistically significant differences between treatment groups [weighted mean difference on a scale of 0–100=9.89 points (–5.05 to 24.83)] (Fig. 2), as the assessment occurred very soon after the intervention. In the intermediate term, two studies [56, 58] were pooled. The results revealed no statistically significant differences between treatment groups with respect to PFM function [weighted mean difference on a scale of 0–100=15.03 points (−9.71 to 39.78)] (Fig. 3). Three studies were not included in the grouping of results because we were unable to extract their mean and standard deviation values [55, 63, 66], and four studies were not included because the studies did not use the same evaluation tools [61, 67–69]. No data were available for quality of life and urinary symptoms.

PFMT with BF versus control group

Two trials with a total of 109 patients compared PFMT with BF and no treatment [65, 67]. The methodological quality of these trials was 6 and 7, respectively. Those studies were not included in the pooled effects calculation because they did not use the same evaluation tools [65, 67].

PFMT with BF versus electrical stimulation

Three trials with a total of 117 patients that compared PFMT with BF and electrical stimulation were included [59–61]. The methodological quality of these trials ranged from 5 to 7. Those studies were not included in the pooled effects calculation because they did not use the same evaluation tools [59–61].

PFMT with BF versus another treatment

Three trials with a total of 463 patients were included. One study compared the efficacy of bladder training, pelvic floor exercises with BF, and combination therapy [62]. Another trial compared PFMT with BF and vaginal cone therapy [63]. The last study evaluated behavioral management for continence, an intervention to manage symptoms of urinary incontinence. The intervention involved self-monitoring, bladder training, and PFM exercises with BF [64]. The methodological quality of these trials ranged from 2 to 6. Two studies were not entered into the pooled effects calculation because the treatment protocols were different [62, 64], and for one study, it was not possible to extract the mean and standard deviation values [63].

BF in the treatment of anorectal dysfunction

Three randomized controlled trials included in this review evaluated BF for the treatment of fecal incontinence (Table 5). Of these, two compared PFMT with BF versus PFMT with BF and electrical stimulation [70, 71], and one compared PFMT with BF and electrical stimulation [72]. These studies treated a total of 133 patients. The methodological quality of these trials ranged from 4 to 7. These studies were not included in the pooled effects calculation

Table 3 PEDro scale for assessment of methodological quality assessment of included studies—sexual dysfunction

Study	E[a]	1	2	3	4	5	6	7	8	9	10	Total score
Bergeron et al. 2001 [73]	+	+	−	+	−	+	+	−	+	+	+	7
Danielsson et al. 2006 [74]	+	+	−	+	−	−	−	−	−	+	+	4
Bergeron et al. 2008 [75]	+	+	−	+	−	+	+	−	−	+	+	6
Bohm-Starke et al. 2007 [76]	+	+	−	−	−	−	−	+	+	+	+	5

E eligibility, *1* random allocation, *2* concealed allocation, *3* baseline comparability, *4* blind subjects, *5* blind therapists, *6* blind assessors, *7* adequate follow-up, *8* intention-to-treat analysis, *9* between-group comparisons, *10* point estimates and variability, + criterion is clearly satisfied, − criterion is not satisfied

[a] Eligibility criteria item does not contribute to total score

Table 4 Details of the included randomized controlled trials—urinary dysfunction

Trial	Participant characteristics, sample size (*N*), duration of symptoms	Interventions and study design	Outcomes (measures) and time points
Shepherd et al. 1983 [66]	Age=23-67 years	PFMT with BF group (mean 6 sessions)—were instructed in a series of graded exercises and given written instructions on how to use the exerciser daily at home	Outcomes = bladder diary, vaginal pressure measurement (cm H_2O)
	N=22	PFMT group (mean 3 sessions)	Pre- and posttreatment evaluations
	Duration of symptoms = (mean 132 months in PFMT and BF; mean 108 in PFMT)	Visual feedback	Follow-up: not reported
	Inclusion criteria = genuine stress incontinence after urodynamic studies were matched with age and parity	Vaginal pressure probe	Results=73 % continent and 18 % improved in the PFMT with BF group
	Main exclusions = not reported		27 % continent and 27 % improved in PFMT group
	Collection type = not reported		
	Educational program = not reported		
	Intervention adherence = not reported		
	Adherence = not reported		
	Dropout rate=27.2 % PFMT		
Ferguson et al. 1990 [57]	Age=37 years	PFMT with BF group	Outcomes = pad test 24 h and 30 min
	N=20	PFMT group	Urodynamic parameters (i.e., maximal urethral pressure, functional urethral length); vaginal pressure measurement (cm H_2O)
	Duration of symptoms = not reported	Both groups asked to perform training of strength and endurance for 10 min/day at home training program for 6 weeks	Pre- and posttreatment, 12- and 24-month follow-up evaluations by letter or telephone (incontinence symptoms of subjects)
	Inclusion criteria = stress urinary incontinence, as defined by the International Continence Society (1979)	The protocols have been described by Dougherty et al. (1989) [84]	Results = there were no significant differences between the groups in urodynamic, pelvic muscle, and urine pad test results
	Main exclusions = Postmenopause, prior urologic surgery, use of drugs that act on the bladder and muscle function, urgency, frequency, or nocturia	Audiotape feedback	
	Collection type = convenience	Vaginal pressure probe	
	Educational program = not reported		
	Intervention adherence = daily record of exercises and contact weekly by telephone		
	Adherence = not reported		
	Dropout rate = not reported		
Burns et al. 1993 [67]	Age=62 years (50–≥75)	PFMT with BF group—8 weeks intervention (8 sessions: 4 sets of 20 fast and sustained contractions—10 quick 3-s holds, 10 sustained 10-s holds, which increased by 10/set over 4 weeks)	Outcomes = urodynamic parameters (i.e., maximal urethral pressure, functional urethral length); EMG pelvic muscle activity; 24-h bladder diary
	N=135	PFMT group—8 weeks intervention (8 sessions: 4 sets of 20 fast and sustained contractions—10 quick 3-s holds, 10 sustained 10-s holds, which increased by 10/set over 4 weeks)	Pre-, during, and posttreatment, 3- and 6-month follow-up evaluations
	Duration of symptoms = not reported	Control group—8 weeks without intervention	Results = severity of incontinence decreased significantly in both treatment groups, but not in the control group, and only BF subjects showed significant improvements in EMGs
	Inclusion criteria = minimum of three urine losses/week, MMSE score≥23, stress or mixed incontinence urodynamic results, absence of glycosuria or pyuria, residual urine<50 cc, peak urinary flow>15 cc	Visual feedback	
	Main exclusions = not reported	Vaginal EMG probe	
	Collection type = random		
	Educational program = subject received a pamphlet that further explained the pelvic anatomy, pelvic floor exercises, and completion of the urine loss and exercise diary		
	Intervention adherence = contact weekly by telephone and exercise reminder cards		
	Adherence = not reported		
	Dropout rate = 7 % withdrew during treatment, 1.4 % lacked complete urinary diaries		
Berghmans et al. 1996 [55]	Age=50 years	PFMT with BF group—EMG activity was sampled 10 times/s; contract/relax session type was used, and the contract/relax period (s), the number of	Outcomes = symptom questionnaire; bladder diary, 48-h pad test, "PERFECT" Assessment

Table 4 (continued)

Trial	Participant characteristics, sample size (*N*), duration of symptoms	Interventions and study design	Outcomes (measures) and time points
		exercise cycles, and treatment times varied for the 12 treatment sessions	Scheme for PFMs (for the planning of the exercise program)
	N=40	PFMT group—4 sets of 10 (5 fast and 5 sustained) and increased by 10/set until 30 times/set + functional training	Pre- and posttreatment evaluations
	Duration of symptoms=1–24 months	Intervention for 4 weeks (three times a week=12 sessions) + homework exercise program to practice 3 times/day	Follow-up: not reported
	Inclusion criteria = women 18-70 years old, medium to moderate stress incontinence (grade I and II), ability to fill out forms, willingness to participate	Visual and acoustical feedback	Results = there was no significant difference in the involuntary loss of urine between the groups. After 12 treatment sessions, there was a mean improvement of ±55 % (p=0.00) in both treatment groups, but only the group biofeedback improvement occurred after the 6th session (p=0.005)
	Main exclusions = pudendal nerve injury, neurogenic bladder, gynecologic or urologic surgery, 6 months after childbirth, grade III and IV stress incontinence, psychological disorders, vaginal irritation, the presence of a pacemaker, hip prosthesis, other forms of treatment for stress incontinence, inability to speak Dutch	Vaginal EMG probe	
	Collection type = convenience		
	Educational program = explanation of the pelvic anatomy, the function of the pelvic floor and bladder, and the use of pelvic exercise		
	Intervention adherence = not reported		
	Adherence=100 % adherence		
	Dropout rate = no dropouts		
Wyman et al. 1998 [62]	Age=61 years	PFMT with BF group—home exercise regimen + 4 office biofeedback sessions. Initially: 5 contractions of 3 s duration and 10 of 10 s/10 s relaxation, 2×/day. After 3 weeks: 10 contractions of 3 s and 40 of 10 s/10 s relaxation, 2×/day. After teaching session: 4 weekly 30-min sessions of visual and verbal biofeedback	Outcomes = bladder diary, pad test, IIQ/R, UDI, subjective evaluation
	N=204	Bladder training group—progressive program that is altered each week on the basis of the patient's progress. Urge inhibition techniques such as affirmations, distraction and relaxation techniques, and voiding interval	Pre- and posttreatment, 3-month follow-up evaluations
	Duration of symptoms=8 years	Combination therapy group—involved the same protocol described above	Results = there was no significant differences between the treatment groups. Combination therapy was as beneficial as any specific treatment
	Inclusion criteria = women in a particular community, 45 years of age or greater, MMSE score>23, urinary incontinence at least once/week, genuine stress incontinence, detrusor instability or both on urodynamic assessment	12 weeks intervention	
	Main exclusions = reversible causes of urinary incontinence, uncontrolled metabolic conditions, residual urine>100 ml, urinary tract infection, genitourinary fistula or catheterization, inability to perform a correct contraction of the PFM	Visual feedback	
	Collection type = convenience	Vaginal pressure probe	
	Educational program = included an audiovisual presentation with written and verbal instruction		
	Intervention adherence = contact biweekly by telephone during treatment; 84 % in the PFMT and BF group; 78 % in the combination therapy group		
	Adherence = not reported		
	Dropout rate=6 % after randomization or during intervention; 8 % in the 3-month follow-up		
Laycock et al. 2001 [63]	Age=20-64 years	PFMT with BF group—individual exercise program was prescribed after digital PFM assessment to determine the strength and duration of maximum voluntary contractions and the number of repetitions that could be performed. A 4-s rest was advised between each maximum contraction. After a short rest, the number of	Outcomes = King's Health Questionnaire, pad test, bladder diary, vaginal pressure measurement (cm H_20)

Table 4 (continued)

Trial	Participant characteristics, sample size (*N*), duration of symptoms	Interventions and study design	Outcomes (measures) and time points
		fast, 1-s maximum contractions was assessed. This series of long and short contractions while supine and then standing for 10 min each day (discontinued during menstruation)	
	N=101	Vaginal cone therapy group—10 min/day, walking around holding the cone in the vagina by actively contracting the PFM, when this was achieved for 2 min, cone retention was practiced during coughing and jumping and when these exercises could be repeated ten times, further weights were added inside the cone (discontinued during menstruation and 2 h after sexual intercourse)	Pre- and posttreatment evaluation
	Duration of symptoms = not reported	PFMT group—individual exercise program was determined after digital vaginal assessment, as described in PFMT with BF. The exercises were performed lying, sitting, and standing for 10 min/day (continued during menstruation)	Follow-up: not reported
	Inclusion criteria = women aged 20–64 years with symptoms of stress urinary incontinence, without clinically significant abnormalities, those able and willing to comply with the trial procedures and give informed consent	3 months home treatment	Results = the methods of treatment resulted in a significant improvement in symptoms of stress urinary incontinence and quality of life
	Main exclusions = pregnancy or planning pregnancy, drugs with action in the lower rinary tract, hormone replacement therapy for less than 3 months, neurological conditions, moderate/severe symptoms of urge incontinence, present or previous participation in research for incontinence, moderate/severe genital prolapse, urinary tract infection	Visual feedback	
	Collection type = convenience	Vaginal pressure probe	
	Educational program = not reported		
	Intervention adherence = six visits to clinic		
	Adherence=77 % vaginal cone therapy; 79 % PFMT with BF; 81 % PFMT		
	Dropout rate = not reported		
Pages et al. 2001 [58]	Age=51 years (27-80)	PFMT with BF group—1 additional individual 30-min session (familiarized with the appropriate use of the biofeedback) + individual therapy for 15 min 5×/week (4 training sets with 10 repetitions each)	Outcomes = bladder diary, subjective evaluation, digital evaluation and vaginal pressure measurement, test speculum
	N=51	PFMT group—group therapy, with 10 patients/group (5×/week=20 sessions) + home exercises (100 contractions during typical daily situations + pelvic floor exercise in supine position for 10 min/twice a day) + exercises for trunk, buttocks, abdominal muscles, and respiratory for general health prevention + aerobic conditioning and assistance in weight reduction (2×/week in a warm water pool for 30 min) + swimming, bicycling, hiking, cross-country skiing	Pre- and posttreatment, 3-month follow-up evaluation
	Duration of symptoms = not reported	4 weeks treatment	Results = PFMT and PFMT with BF are effective therapies for female urinary stress incontinence, able to reduce nocturia/urinary frequency and to improve quality of life. PFMT with BF resulted in higher contraction pressure of the PFM
	Inclusion criteria = average/moderate stress urinary incontinence, candidates for nonsurgical treatment, ability to consciously activate PFMs	After 4 weeks treatment all patients continued doing exercises once daily at home without apparatus	
	Main exclusions = neurological diseases, drugs that act to increase bladder control	Visual feedback	
	Collection type = convenience	Vaginal pressure probe	
	Educational program = one session in which patients were informed about the function of PFMs with the use of anatomical models and illustrations		
	Intervention adherence = not reported		
	Adherence = not reported		
	Dropout rate=45 % in PFMT with BF group after randomization (cystitis, genital prolapse, gynecological hemorrhage or decision to withdraw)		
	Age=68 years (55–95)		

Table 4 (continued)

Trial	Participant characteristics, sample size (*N*), duration of symptoms	Interventions and study design	Outcomes (measures) and time points
Dougherty et al. 2002 [64]		Behavioral management for continence group—self-monitoring: reducing caffeine consumption, adjusting the amount and timing of intake, decreasing excessively long voiding intervals during awake hours and making dietary changes to promote bowel regularity (2–4 weeks) + bladder training: implemented with a protocol by Wyman and Fantl (1991) [85] (6–8 weeks) + pelvic floor exercise with biofeedback (12 weeks—15 repetitions/day increased every 3 weeks to 45 contractions/day, 3×/week)	Outcomes = bladder diary, pad test, IIQ, subjective evaluation
	N=138	Control group—no treatment	Pre- and posttreatment, 6-, 12-, 18-, and 24-month evaluations
	Duration of symptoms=12 years	12 weeks treatment	Results = in the 2-year follow-up, behavioral management for continence in the urinary incontinence group decreased severity by 61 %, and the control group increased incontinence severity by 184 %. The primary reasons for improvement were self-monitoring and bladder training
	Inclusion criteria=≥ 55 years and live in private residence, urinary loss of 1 g/24 h or+≥ 2 times /week, symptoms of stress and mixed urinary incontinence, urge incontinence, urine negative for bacteria	Visual feedback	
	Main exclusions = bladder cancer or renal disease, residual urine≥100 cc		
	Collection type = convenience		
	Educational program = not reported		
	Intervention adherence = not reported		
	Adherence=82 %		
	Dropout rate=21 % behavioral management for continence group; 15 % control group		
Mørkved et al. 2002 [56]	Age=47 years	PFMT with BF group—3 sets of 10 contractions—6–8 s endurance, add 3–4 fast contractions, 1×/week for 2 months and 1×/month for 4 months + home training: 3 sets of 10 contractions daily	Outcomes = subjective evaluation, 48-h pad test, loss rate, social activity, vaginal palpation, and vaginal pressure measurement
	N=103	PFMT group—3 sets of 10 contractions—6–8 s endurance, add 3–4 fast contractions, 1×/week for 2 months and 1×/month for 4 months + home training: 3 sets of 10 contractions daily	Pre- and posttreatment evaluations
	Duration of symptoms=10 years	24 weeks intervention	Follow-up: not reported
	Inclusion criteria = history of stress urinary incontinence, pad test>2 g	? Feedback	Results = both groups showed a significant reduction in leakage on pad tests after treatment. Objective cure (< 2 g pad test of leakage) was achieved in 58 % of those in the PFMT with BF group and in 46 % of those in the PFMT group
	Main exclusions = involuntary detrusor contraction on cystometry, residual urine>50 ml, previous surgery for stress urinary incontinence, neurological/psychiatric disease, urinary tract infection, pregnancy, concomitant treatments during the study, inability to understand the instructions in Norwegian	Vaginal pressure probe	
	Collection type = random		
	Educational program = individually instructed in pelvic floor anatomy and how to contract the PFMs correctly		
	Intervention adherence = individual training sessions, motivation, and monitoring of PFM strength		
	Adherence=85.3 % PFMT; 88.9 % PFMT with BF		
	Dropout rate=8.7 %		
Aukee et al. 2002 [68]	Age=51 years (21–70 years)	PFMT with BF group—visited the physiotherapist 5 times (0, 1, 4, 8, 12 weeks)—each session: 3 contractions of 5 s with 10-s intervals in the supine and standing position + home training: 20 min/day 5×/week	Outcomes = EMG PFM activity (supine and standing), 24-h pad test, loss rate
	N=30	PFMT group—visited the physiotherapist 5 times (0, 1, 4, 8, 12 weeks)—each session: 3 contractions of 5 s with 10-s intervals in the	Pre- and posttreatment evaluations

Table 4 (continued)

Trial	Participant characteristics, sample size (*N*), duration of symptoms	Interventions and study design	Outcomes (measures) and time points
		supine and standing position + home training: 20 min/day 5×/week	
	Duration of symptoms=9 years	12 weeks intervention	Follow-up: Aukee et al. 2004 [69]
	Inclusion criteria = stress urinary incontinence in urodynamic testing, without previous incontinence operations, maximal urethral closure over 90 cm H_2O	Visual feedback—clinic	Results = significant improvements in PFM activity and the urine leakage index in the biofeedback group compared with the PFMT group
	Main inclusion = genital protrusion beyond the vaginal hymen, inability to understand instructions for home training, pregnancy, abdominal malignancies, multiple sclerosis, diabetes mellitus requiring insulin	Audio feedback—home	
	Collection type = convenience	Vaginal EMG probe	
	Educational program = instruction on the location f the levator ani muscle and the pelvic anatomy		
	Intervention adherence = not reported		
	Adherence = not reported		
	Dropout rate=13 % PFMT with BF		
Aksac et al. 2003 [65]	Age=54 years	PFMT with BF group—the BF was performed in lithotomy position 3 times/week for 8 weeks; 20 min (40 cycles with 10 s activity followed by 20 s relaxation)	Outcomes = digital palpation and vaginal pressure measurement (cm H_2O) PFM, 1-h pad test, incontinence frequency, index of social activity, visual analog scale
	N=50	PFMT with vaginal palpation group—home training: contract 5 s/10 s relax—10×/session, 3 sessions/day; 2 weeks later contract 10 s/20 s relax + weekly follow-up sessions for 8 weeks. To perform the exercises correctly, they were told to act as if they were interrupting micturition	Pre- and posttreatment evaluations
	Duration of symptoms = not reported	Control group—hormone replacement therapy (estradiol hemihydrate 2 mg/day and norethisterone acetate 1 mg/day)	Follow-up: not reported
	Inclusion criteria = urodynamically determined stress urinary incontinence	8 weeks intervention	Results = cure rates reported as less than 2 g of leakage measured with the pad test: PFMT with vaginal palpation had a 75 % cure rate and an improvement rate of 25 %, while PFMT with BF had an 80 % cure rate and a 20 % improvement rate; the control group had no cures and a 20 % improvement rate
	Main exclusions = not reported	? Feedback	
	Collection type = convenience	Vaginal EMG probe	
	Educational program = not reported		
	Intervention adherence = not reported		
	Adherence = not reported		
	Dropout rate = not reported		
Wang et al. 2004 [61]	Age=55 years	PFMT with BF group—contract or relax PFM following visual EMG signs, 2×/week + PFM contraction according to PERFECT scheme for home program	Outcomes = 7-day bladder diary, 1-h pad test, King's Health Questionnaire, PERFECT scheme, and vaginal pressure measurement
	N=120	For example, if the PERFECT scheme was 3/6/5/10 (power/endurance/repetition/fast contractions), the patient was instructed to hold submaximal to maximal PFM contractions for 6 s 5 times and to perform 10 fast contractions/session	Pre- and posttreatment evaluations
	Duration of symptoms = not reported	PFMT group—PFM contraction according to PERFECT scheme, 3×/day	Follow-up: not reported
	Inclusion criteria = women 16–75 years, symptoms of overactive bladder for more than 6 months, urinary frequency≥8/day, urge incontinence≥1 time or more /day	Electrical stimulation group—frequency 10 Hz, pulse width 400 μs, cycle 10 s on, 5 s off and intensity with patient tolerance, 20 min/session, 2×/week	Results = electrical stimulation resulted in the highest rates of improvement/cure (51.4 %) and was the most effective treatment. PFMT with BF was more effective than PFMT alone
	Main exclusions = pregnancy, deafness, neurological diseases, diabetes mellitus, pacemaker, intrauterine device, pelvic organ prolapse grade II, residual urine>100 ml, urinary tract infection	12-week intervention	
	Collection type = convenience	Visual feedback	
	Educational program = not reported	Vaginal EMG probe	
	Intervention adherence = not reported		
	Adherence=0.83 % PFMT; 0.75 % PFMT with BF; 0.79 % electrical stimulation		

Table 4 (continued)

Trial	Participant characteristics, sample size (*N*), duration of symptoms	Interventions and study design	Outcomes (measures) and time points
	Dropout rate=17 % PFMT; 11.76 % PFMT with BF; 20 % electrical stimulation		
Aukee et al. 2004 [69] (follow-up Aukee et al. 2002 [68])	51 years	PFMT with BF group—visited the physiotherapist 5 times (0, 1, 4, 8, 12 weeks) – each session: 3 contractions of 5 s with 10-s intervals in the supine and standing position + home training: 20 min/day 5×/week	Outcome = EMG PFM, loss rate, subjective assessment (5-point scale)
	N=35	PFMT group—visited the physiotherapist 5 times (0, 1, 4, 8, 12 weeks)—each session: 3 contractions of 5 s with 10-s intervals in the supine and standing position + home training: 20 min/day 5×/week	12-month follow-up evaluation
	Duration of symptoms=8 years	12 weeks intervention	Results = the benefits of the biofeedback device resulted in a greater increase in muscle activity and improved continence more than PFMT alone
	Inclusion criteria = women 21–70 years with stress urinary incontinence and abdominal leak point pressure greater than 90 cm H_2O, maximal closure pressure over 20 cm H_20, without previous incontinence operations	Visual feedback—clinic	
	Main exclusions = genital protrusion beyond the vaginal hymen, surgery for urinary incontinence, inability to understand the instructions for home training, pregnancy, abdominal malignancies, multiple sclerosis, insulin-dependent diabetes	Audio feedback—home	
	Collection type = convenience	Vaginal EMG probe	
	Educational program = instruction on the location of the levator ani muscle and the pelvic anatomy		
	Intervention adherence = not reported		
	Adherence = not reported		
	Dropout rate=12.5 % PFMT with BF group		
Demirtürk et al. 2008 [59]	Age=50 years	Biofeedback group—the protocol was individually designed, the patients performed 15 min pelvic floor exercise, 3×/week=15 sessions	Outcomes = 1-h pad test, EMG PFM activity, quality of life questionnaire
	N=41	Current interferential group—frequency 0–100 Hz, 15 min, 3×/week=15 sessions	Pre- and posttreatment evaluations
	Duration of symptoms=6.5 years	6 weeks intervention	Follow-up: not reported
	Inclusion criteria = moderate urinary incontinence on the 1-h pad test	? Feedback	Results = both methods can be used effectively in patients with urinary stress incontinence
	Main exclusions = urinary tract infection, detrusor instability, cognitive problems, neoplasm	Vaginal EMG probe	
	Collection type = convenience		
	Educational program = not reported		
	Intervention adherence = not reported		
	Adherence = not reported		
	Dropout rate = not reported		
Schmidt et al. 2009 [60]	Age=54 years	PFMT with BF group—series of fast contractions (2 s and 4 s of rest) followed by series of slow contractions (4 s and 4 s of rest) repeated 3 times with a rest interval	Outcomes = vaginal pressure measurement, bladder diary, King's Health Questionnaire, urodynamic analyses
	N=32	PFMT group—series of fast contractions (2 s and 4 s of rest) followed by series of slow contractions (4 s and 4 s of rest) repeated 3 times with a rest interval	Pre- and posttreatment, 3-month follow-up evaluations
	Duration of symptoms = not related	PFMT combined with electrical stimulation group—series of fast contractions (2 s and 4 s of rest) followed by series of slow contractions (4 s and 4 s of rest) repeated 3 times with a rest interval + 50 Hz frequency stimulation and pulse of 300 μs	Results = all 3 treatments were effective for home treatment of urinary incontinence, with significant control of symptoms and improved quality of life
	Inclusion criteria = women>30 years, stress urinary incontinence or mixed, pelvic prolapse<2 °, not receiving clinical or surgical treatment during previous 6 months, absence of leak point pressure< 60 cm H_2O	This exercise cycle aims to recruit type 1 and type 2 fibers [86]	
	Main exclusions = not reported	12 weeks training	
	Collection type = convenience	Both groups were directed to continue the exercises at home without the equipment after treatment	
	Educational program = description of the pelvic musculature, anatomical position, the function of	Visual feedback	

Table 4 (continued)

Trial	Participant characteristics, sample size (*N*), duration of symptoms	Interventions and study design	Outcomes (measures) and time points
	the exercises to strengthen this musculature, and its relationship to urinary continence		
	Intervention adherence = not reported	Vaginal pressure probe	
	Adherence = not reported		
	Dropout rate = not reported		

PFMT with BF pelvic floor muscle training with biofeedback, *PFMT* pelvic floor muscle training, *EMG* electromyography, *PFM* pelvic floor muscle, *MMSE* Mini-Mental State Examination, *IIQ/R* Incontinence Impact Questionnaire/Revised, *UDI* Urogenital Distress Inventory, Subjective evaluation, *IIQ* Incontinence Impact Questionnaire

because we were unable to extract the values for the means and standard deviations.

BF in the treatment of sexual dysfunction

Four randomized controlled trials were included in this review of BF as treatment for sexual dysfunction (Table 6). Among these studies, one compared vestibulectomy, PFMT with BF, and cognitive behavioral therapy in the treatment of dyspareunia resulting from vulvar vestibulitis [73]. Two studies compared PFMT with BF and topical lidocaine gel for the treatment of vulvar vestibulitis [74, 76], and one was a follow-up study by Bergeron et al. 2001 [75]. These studies included a total of 173 patients. The methodological quality of these trials ranged from 4 to 7. Only one study included data concerning the mean and standard deviation [73, 75]. These studies were not included because the aim of this review was to combine data from many studies to obtain a pooled result.

Discussion

In this systematic review, we compared the effects of PFMT with BF versus other forms of treatment for patients with PFM dysfunction. Using the pooled effects calculations, we did not observe advantages with the use of BF in conjunction with PFMT over other conservative treatments.

In the studies related to the treatment of urinary dysfunction, PFMT with BF was compared to PFMT alone. The results favored the use of PFMT alone in the PFM function evaluation; however, the difference was not significant in either the short or intermediate term. Four of these studies [57, 58, 60, 65] showed that both PFMT with BF and PFMT alone were effective for treating urinary incontinence. However, Pages et al. [58] and Aksac et al. [65] reported that PFMT with BF resulted in improved PFM function, as evidenced by a higher contraction pressure and strength of the PFM. In other studies, the addition of BF to PFMT showed no significant effects; however, the authors reported that the use of an apparatus during training may motivate many women and that it should be an option in clinical practice [56]. Increased awareness is thought to motivate patients to perform exercises that restore function and health [77]. In four studies, patients had received information regarding the anatomy of the PFM, the function of the exercises to strengthen this musculature, and the relation of such exercises to urinary continence [56–58, 60]. One study reported regular measurement of muscle strength by a skilled physical therapist to achieve this effect [56]. In another study, the PFMT group performed the exercises using the digital palpation technique, while the patients were instructed to perform the proper contraction. They were instructed "to stop the micturition" [65]. Another factor that may have affected the results was the low number of participants in the studies

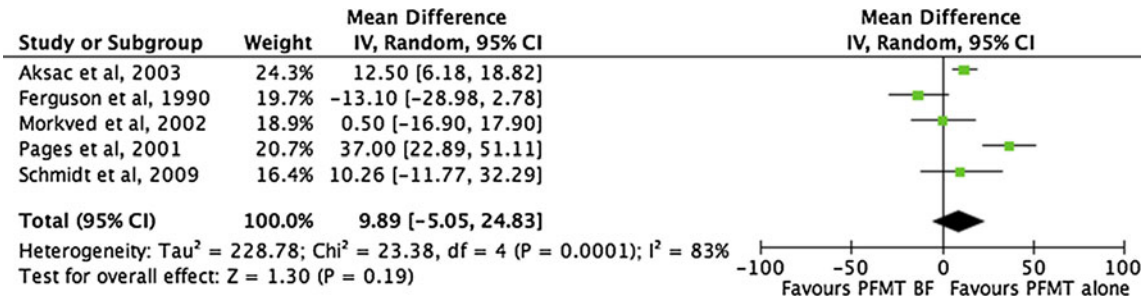

Fig. 2 Forest plot of results from randomized controlled trials comparing PFMT with BF and PFMT alone in the treatment of urinary dysfunction. Evaluation of PFM function in the short term by the vaginal pressure measurement. Values represent effect sizes (weighted mean differences) and 95 % confidence intervals. The pooled effect sizes were calculated using a random effects model

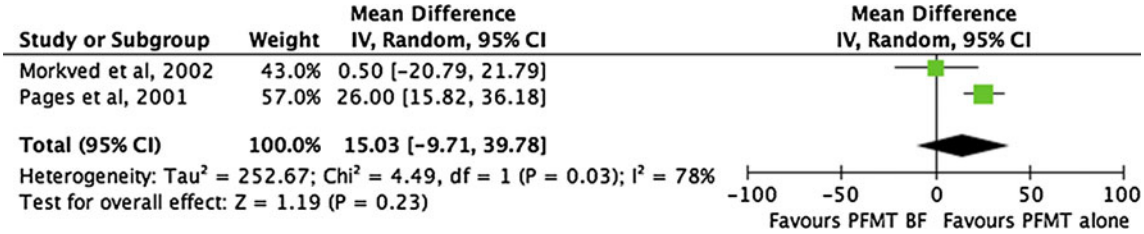

Fig. 3 Forest plot of results from randomized controlled trials comparing PFMT with BF and PFMT alone in the treatment of urinary dysfunction. Evaluation of PFM function in the intermediate term by the vaginal pressure measurement. Values represent effect sizes (weighted mean differences) and 95 % confidence intervals. The pooled effect sizes were calculated by using a random effects model

included in the analysis. When the studies of PFM effects in the short term were combined, the PFMT with BF group had 101 patients, and the PFMT alone group had a total of 114 patients from the five studies included. In the analysis of intermediate-term effects, only two studies were included in the analysis, yielding a total of 61 patients in the PFMT with BF group and 73 in the PFMT alone group.

In the quality of life evaluation, it was not possible to pool an effect size for the meta-analysis. Several types of instruments were used to evaluate the quality of life. Among the studies that could be brought together in the meta-analysis, two studies evaluated quality of life using the King's Health Questionnaire; however, the statistical analysis and the results were presented in different ways. One study [60] presented the total score of the questionnaire, whereas another study [61] presented results comparing the domains separately. Schmidt et al. [60] did not find a significant difference between groups on overall scores, but a significant reduction in subjective perception of the impact of the incontinence during the treatment period was observed. Wang et al. [61] had already reported the absence of a statistically significant impact on incontinence; however, the scores for overall quality of life were significantly greater after PFMT with BF. Therefore, PFMT with BF resulted in a better quality of life than PFMT alone after treatment.

A similar problem was observed regarding symptom evaluation. A bladder diary [55, 58, 60, 63], 7-day bladder diary [61], urodynamic analyses [57, 60, 61, 67], 1-h pad test [61, 65], 24-h pad test [57, 68], urine loss rate [56, 68, 69], 48-h pad test [56], 24-h bladder diary [67], incontinence frequency [65], and 30-min pad test [57] were used to evaluate the outcomes of PFMT with BF and PFMT alone. Although some studies used the same assessment tool, the protocols were different. Besides, there is a lack of information on how the evaluation was performed. For example, among studies that used the bladder diary only two describe the use of a 7-day and 24-h bladder diary [61, 67]. In studies where the 1-hour pad test was used, only one of them presents the results [65]. In urodynamic analyses, one study does not present the results [61], and in others, the method of performing the test differs among the studies [57, 60, 67]. As a result, it is impossible to gather the studies to perform the meta-analysis.

None of the studies in which PFMT with BF was compared with a control group was included in the pooled effects calculation [65, 67]. A variety of assessment tools have been used to confirm the outcomes of treatment programs for PFM disorders. Aksac et al. [65] used as outcome measures: digital palpation and vaginal pressure measurement of PFM, 1-h pad test, incontinence frequency, index of social activity, and visual analog scale, whereas Burns et al. [67] used urodynamic parameters (i.e., maximal urethral pressure, functional urethral length), EMG pelvic muscle activity, and 24-h bladder diary. The heterogeneity of the studies has been a limiting factor for the conclusion of this study.

With regards to studies that compared PFMT with BF and electrical stimulation, none were included in the pooled effects calculation. In the evaluation of quality of life, two studies used the King's Health Questionnaire, although, as mentioned above, the calculation of the score was performed differently. Schmidt et al. [60] calculated the total score and did not find a significant difference among the groups. Wang et al. [61] calculated the domains separately, and the data between the PFMT with BF group and the electrical stimulation group revealed statistically significant differences with respect to the emotions (p=0.003) and severity (p=0.029) domains, but not in the total score (p=0.952). Demirtürk et al. [59] found an improved quality of life in both modalities (p<0.05). Each of these studies evaluated outcomes in the short term.

Regarding symptom evaluation, one study opted not to use episodes of leakage per day due to the large number of incomplete records, which could bias the results [61]. Two studies found significant decreases in the number of stress leakages assessed by the bladder diary and pad test (p< 0.05) [59, 60] in the short term. Another study compared PFMT with BF, low-intensity electrical stimulation at home, and maximal electrical stimulation in the clinic. There were significant reductions in urine loss for all three groups after 6 months of treatment; however, the

Table 5 Details of included randomized controlled trials—anorectal dysfunction

Trial	Participant characteristics, sample size (*N*), duration of symptoms	Interventions and study design	Outcomes (measures) and time points
Fynes et al. 1999 [70]	Age=32 years (18–48)	PFMT with BF group—30 min each week for 12 weeks, 20 contractions of 6–8 s duration, with 10-s intervals of relaxation. Slow contractions were performed aiming to achieve a contraction of at least 30 s duration. These exercises were performed in the supine position	Outcomes = symptoms questionnaire (Pescatori et al. [83]); anal manometry; pudendal nerve terminal motor latency; anal endosonography
	N=40	PFMT with BF + electrical stimulation (anal EMG probe) group—training was performed with the patients lying in the left lateral position. Static and dynamic exercises were alternated over a 15-min period comprising 13-s cycles (5 s duration, with 8 s relaxation) + 20 Hz for 10 min with 5 s stimulation and 8 s relaxation; 50 Hz for 8 s with 30 s rest	Pre- and posttreatment evaluations
	Duration of symptoms=4 months (3–28)	12 weeks intervention	Follow-up: not reported
	Inclusion criteria = fecal incontinence after obstetric trauma	Vaginal pressure probe	Results = PFMT with BF + electrical stimulation is superior to PFMT with BF
	Main exclusions = not reported	Audiovisual feedback	
	Collection type = convenience		
	Educational group = not reported		
	Intervention adherence = not reported		
	Adherence = not reported		
	Dropout rate=2.5 % PFMT with BF group		
Mahony et al. 2004 [71]	Age=35 years	PFMT with BF group—slow muscle contraction exercises for 5 s with relaxation for 8 s, alternating with fast exercises, 3 fast maximal squeeze contractions	Outcomes = continence score (0–20); anorectal manometry; endoanal ultrasound, FIQLS
	N=60	PFMT with BF + electrical stimulation group—the same protocol as above + 35 Hz with 20 % ramp modulation time, 20 min with 5 s of stimulation and 8 s relaxation between contractions	Pre- and posttreatment evaluations
	Duration of symptoms = not reported	All patients performed exercises daily for the 12-week intervention	Follow-up: not reported
	Inclusion criteria = symptoms of fecal incontinence after obstetric trauma	Visual feedback	Results = PFMT with BF was associated with improved continence and quality of life. The addition of electrical stimulation of the anal sphincter did not enhance symptomatic outcome
	Main exclusions = diabetes mellitus, inflammatory bowel disease, irritable bowel syndrome, previous anorectal surgery or malignancy	Anal EMG probe	
	Collection type = convenience		
	Educational program = not reported		
	Intervention adherence = not reported		
	Adherence = not reported		
	Dropout rate=13 % PFMT with BF group; 6 % PFMT + electrical stimulation group		
Naimy et al. 2007 [72]	Age=36 years (22–44)	PFMT with BF group—squeezes of 3 and 10 s with equal lengths of rest, repeated 5 times. Instruction given twice to ensure that the patient understood the treatment; home training of 30 min with sessions 2×/day	Outcomes = Wexner anal incontinence score; FIQLS, visual analog scale (0–10, for reduced quality of life and treatment effect)
	N=49	Electrostimulation group—3 s stimulation (30–40 Hz/200 μs followed by 3 s rest for 20 min + home training of 20-min sessions 2×/day	Pre- and posttreatment evaluations
	Duration of symptoms = not reported	8 weeks intervention	Follow-up: not reported
	Inclusion criteria = some degree of incontinence after grade 3 or 4 perineal rupture	? Feedback	Results = there were no differences in treatment effect between groups. Despite this, the treatment showed a subjective perception of incontinence control
	Main exclusions = anal sphincter defect requiring surgery or secondary repair of the anal sphincter <12 months previously, pregnancy, inflammatory bowel disease, or diarrhea due to other reasons	Anal EMG probe	
	Collection type = convenience		
	Educational program = not reported		
	Intervention adherence = not reported		

Table 5 (continued)

Trial	Participant characteristics, sample size (*N*), duration of symptoms	Interventions and study design	Outcomes (measures) and time points
	Adherence = not reported Dropout rate=20.83 % due to intensive treatment and other reasons; 16 % because of discomfort and other reasons		

PFMT with BF pelvic floor muscle training with biofeedback, *PFMT* pelvic floor muscle training, *EMG* electromyography, *PFM* pelvic floor muscle, *FIQLS* Fecal Incontinence Quality of Life score

strongest evidence for improvement occurred in the clinical treatment group (p=0.0003) in the intermediate term. In the long term, all groups demonstrated a further reduction in urine loss at pad testing.

For PFM evaluation, two studies found improvements after treatment in each group, and both treatment modalities seemed to have similar effects on PFM evaluation [59, 60]. Wang et al. [61] found improvement in vaginal pressure for the PFMT with BF group, demonstrating a 105 % increase after treatment, whereas electrical stimulation only yielded an increase of 12.63 %. However, the authors stated that muscle strength is not a good measurement of overactive bladder, and the preferred measurement of overactive bladder might be an evaluation of urinary symptom reduction or improvement in quality of life.

With regard to the studies in which PFMT with BF was used as treatment for anorectal dysfunction, no studies were included in the pooled results calculation due to the inability to extract the mean and standard deviation values for analysis. In the comparison between BF and electrical stimulation, Naimy et al. [72] found no difference between groups regarding quality of life, symptoms of anal incontinence, and subjective perceptions of incontinence control. In two studies, BF was compared with BF and electrical stimulation for fecal incontinence, and the results between the two studies were divergent. Mahony et al. [71] did not find any additional benefit of electrical stimulation on symptom outcome. However, Fynes et al. [70] found that the outcome for the BF group with electrical stimulation was superior to that of the group that used BF alone. This may have occurred because Mahony et al. [71] used stimulation frequencies of approximately 35 Hz, whereas Fynes et al. [70] used both smaller frequencies (about 20 Hz) and larger frequencies (about 50 Hz).

In studies wherein PFMT with BF was used to treat sexual dysfunction, only one presented the results in mean and standard deviation. These studies were not included because the aim of this review was to combine many studies to determine pooled results. Both studies included in this review treated vestibular pain. Only the results of the comparison between the conservative interventions are discussed. All studies found significant improvements in measurements posttreatment. In the study by Bergeron et al. [73], both the PFMT with BF and cognitive behavioral therapy groups showed significant improvements in psychological adjustment and sexual functioning at a 6-month follow-up, persisting up to the 2-year follow-up. One factor that may be responsible for these results is the fact that, in both groups, Kegel exercises were conducted. In the cognitive behavioral therapy group, the exercises were not practiced with the same intensity as in the PFMT with BF group. The authors claim that training with BF reduces the instability and hypertonicity of the PFM. Reestablishment of muscle function with an improved capacity to relax the pelvic floor during sexual activity is thought to reduce coital pain. In another study, PFMT with BF was compared with lidocaine treatment. Despite the high dropout rate in the PFMT with BF group, Danielsson et al. [74] found that there were significant improvements in both groups after treatment. Thus, if the PFMT with BF group had had better compliance with the treatment, the result could have been more satisfactory. Indeed, patient compliance is very important, as the effect of the treatment is dependent on it, which has been demonstrated in several previous studies [78–80].

Unfortunately it was not possible to perform the calculation of effect size by reviewing studies that address the treatment of sexual and anorectal dysfunction. A major reason was the number of included studies. Nevertheless, we would like to emphasize the necessity of randomized, controlled, and well-designed studies assessing the use of BF to treat these disorders and the need to conduct new research which, when considered together, will be able to achieve a conclusion.

Patient compliance is considered important in physical therapy, as treatment effects are partially dependent on it. The efficacy of therapeutic exercises can only be established when patients adhere to the exercise regimen [81]. Patients adhere better to treatment when they perceive no barriers, are extensively instructed, and receive positive feedback [82]. In the studies included in this review, only one study reported 100 % adherence [55]. As previously mentioned, BF is used as a technique that provides motivation for patients to perform PFM exercises and as a form of awareness of the PFMs. For

Table 6 Details of included randomized controlled trials—sexual dysfunction

Trial	Participant characteristics, sample size (*N*), duration of symptoms	Interventions and study design	Outcomes (measures) and time points
Bergeron et al. 2001 [73]	Age=26 years	PFMT with BF group—protocol: one 60-s pre-baseline rest period; 6 maximum-intensity 12-s contractions or flicks (phasic), each contraction being preceded by a 12-s rest period; 6 maximum-intensity 12-s contractions or flicks (tonic), each contraction being preceded by a 12-s rest period; one maximum-intensity 60-s contraction (endurance) preceded by a 30-s- rest; one 60-s post-baseline rest period, for eight 45-min sessions over a 12-week period + two daily sessions biofeedback home trainer (60 repetitions and a 10-s relaxation period alternated with a 10-s maximum contraction period	Outcomes = VPI; PRI-MPQ; assessment of intercourse pain intensity (scale 0–10); GSFS; SHF; SISDSFI; measuring the frequency of intercourse/month; BSI-GSI; assessment of improvement (scale 0–5) and treatment satisfaction (scale 0–10)
Bergeron et al. 2008* [75]	*N*=87	Vestibulectomy group—to receive information regarding the procedure before surgery and receive instructions concerning how to gradually resume intercourse 6 weeks after surgery	Pre- and posttreatment evaluations
	Duration of symptoms=57 months	GCBT group—education and information about vulvar vestibulitis and how dyspareunia impacts desire and arousal; education on a multifactorial view of pain, education about sexual anatomy, progressive muscle relaxation, abdominal breathing, Kegel exercises, vaginal dilatation, distraction techniques focusing on sexual imagery, rehearsal of coping self-statements, communications skills training, and cognitive restructuring, for 8 over a 12-week period	6 months follow-up evaluations
	Inclusion criteria = pain during intercourse, which is subjectively distressing, occurs on most intercourse attempts and has lasted for at least 6 months; women who stopped attempting intercourse as a result of the pain; if the pain could be confirmed during the gynecological examinations; pain limited intercourse and other activities involving vestibular pressure; moderate to severe pain in one or more locations of the vestibule during the cotton swab test	Visual feedback	*2/5-year follow-up evaluation
	Main exclusions = vulvar or pelvic pain unrelated to intercourse, active infection, psychiatric disorders, vaginismus, ongoing dyspareunia treatment, pregnancy, age<18 and>50	Vaginal EMG probe	Results = all groups showed significant improvement in pain, but vestibulectomy obtained better results
	Collection type = convenience		6-month follow-up, all 3 groups significantly improved on measures of psychological adjustment and sexual function
	Educational program = not reported		2/5-year follow-up, treatment gains were maintained
	Adherence intervention = not reported		
	Adherence = not reported		
	Dropout rate=16.6 % all groups		
Danielsson et al. 2006 [74]	Age=25 years	PFMT with BF group—home training (3 daily 10-min sessions: 10 maximal-intensity 5-s contractions, followed by a 5 s rest, 10 contractions repeated once after a 60-s rest; 15 maximal-intensity, 10-s rest; one maximal-intensity 60-s contraction) + 4 evaluations in the office	Outcomes = pressure pain threshold, SF-36; PRIME MD; VAS (000–100) (QOL, sexual function and pain on intercourse)
	Duration of symptoms=38 months	Lidocaine group—application of the gel to painful areas of the vestibule 5–7×/day for the first 2 months; the ointment was recommended in the same way for the subsequent 2 months provided it provoked no pain + 3 evaluations in the office	Pre- and posttreatment, 6- and 12-month follow-up evaluations
	N=46	4 months intervention	Results = the study showed that the treatment significantly improved vestibular pain, sexual functioning, and psychosocial adjustments at the 12-month follow-up. No differences were observed in outcome between the two groups. A combination of both could convey benefits to women with vulvar vestibulitis
	Inclusion criteria = introital pain, severe vestibular tenderness to pressure from a cotton swab, moderate to pronounced pain during most intercourse attempts, duration of symptoms≥6 months and age≥18 years	? Feedback	
	Main exclusions = psychological disorders, severe psychiatric and medical conditions,	Vaginal EMG probe	

Table 6 (continued)

Trial	Participant characteristics, sample size (*N*), duration of symptoms	Interventions and study design	Outcomes (measures) and time points
	pregnancy, prior vestibulectomy, or behavioral therapy		
	Collection type = convenience		
	Educational program = not reported		
	Adherence intervention = not reported		
	Adherence = not reported		
	Dropout rate=19.6 % because of lack of motivation, moving out of the region, broken relationship, and candida infection		
Bohm-Starke et al. 2007 [76]	25 years	EMG biofeedback group —10 min of practice 2×/day for 4 months. The protocols have been described by Danielsson et al. (2006) [74]	Outcomes = pain threshold assessment; SF-36; subjective outcome and bodily pain
	Duration of symptoms=36 months	Topical lidocaine group—applied on the vestibule 5×/day for 4 months	Pre, post and 6-month follow-up evaluations
	N=35 (patients), 30 (healthy controls)	Healthy control group—half of the women were using combined oral contraceptives, and the other half was using no hormonal contraceptive methods	Results = no differences in outcome measures were observed between the two groups. Of the patients, 3/35 reported a total cure, and 35/35 reported symptom improvement
	Inclusion criteria = provoked introital pain, moderate to pronounced pain during most intercourse attempts, duration of symptoms≥6 months and age≥18 years	4 months intervention	
	Main exclusions = patients with severe medical, psychiatric, or psychological disorders, pregnancy	? Feedback	
	Collection type = convenience	Surface EMG	
	Educational program = not reported		
	Adherence intervention = not reported		
	Adherence = not reported		
	Dropout rate = not reported		

PFMT with BF pelvic floor muscle training with biofeedback, *PFMT* pelvic floor muscle training, *EMG* electromyography, *PFM* pelvic floor muscle, *VPI* vestibular pain index, *PRI-MPQ* Pain Rating Index of the McGill Pain Questionnaire, *GSFS* Global Sexual Functioning score, *SHF* Sexual History Form, *SISDSFI* Sexual Information Scale of the Derogatis Sexual Functioning Inventory, *BSI-GSI* Global Severity Index of the Brief Symptom Inventory, *PRIME MD* Primary Care Evaluation of Mental Disorders, *SF-36* 36-Item Short-Form Health Survey, *QOL* quality of life, *VAS* visual analog scale

PFMT with BF, the patient's awareness of PFM is critical, as conscious activation of PFMs is a requirement for strength training [58].

There are some limitations to the conclusions of this review. These include the low quality of the studies, the use of various types of outcomes, and the differences in the implementation of the interventions. The results of this systematic review suggest that PFMT with BF is not more effective than other conservative treatments for female PFM dysfunction.

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Conflicts of interest None.

Appendix

Search strategies

PEDro

Therapy: no selection
Problem: incontinence
Body part: perineum or genitourinary system
Subdiscipline: continence and women's health
Method: clinical trial
Match all search terms (AND)
Therapy: no selection
Problem: motor incoordination
Body part: perineum or genitourinary system
Subdiscipline: continence and women's health
Method: clinical trial
Match all search terms (AND)
Therapy: no selection
Problem: muscle weakness
Body part: perineum or genitourinary system
Subdiscipline: no selection
Method: clinical trial
Match all search terms (AND)

MEDLINE/LILACS

1. ((biofeedback and (muscle and pelvic and floor))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND

([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

2. ((biofeedback and (urinary and incontinence))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

3. ((biofeedback and (urinary and incontinence and muscle and pelvic and floor))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

4. ((biofeedback and (stress and urinary and incontinence))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

5. (biofeedback and (overactive and bladder))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

6. ((biofeedback and pelvic and floor and exercises)) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

7. ((biofeedback and neuromuscular and electrical and stimulation)) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

8. ((biofeedback and (fecal and incontinence))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

9. ((biofeedback and (anal and incontinence))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

10. ((biofeedback and (anal and incontinence and muscle and pelvic and floor))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

11. ((biofeedback and (fecal and incontinence and muscle and pelvic and floor))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

12. ((biofeedback and (intestinal and constipation))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

13. ((biofeedback and (constipation))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

14. ((biofeedback and (dyspareunia))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

15. ((biofeedback and (sexual and dysfunction))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

16. ((biofeedback and (sexual))) AND ([CT] humano or humanos) AND ([CT] FEMININO) AND ([PT] ENSAIO CLINICO CONTROLADO OR ENSAIO CONTROLADO ALEATORIO) [Palavras]

17. biofeedback and (vaginismus) AND Espécie = Humanos AND Gênero = Feminino AND Tipo de publicação = Ensaio clínico controlado

PubMed

1. (("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("pelvic floor"[MeSH Terms] OR ("pelvic"[All Fields] AND "floor"[All Fields]) OR "pelvic floor"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

2. (("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("muscles"[MeSH Terms] OR "muscles"[All Fields] OR "muscle"[All Fields]) AND ("pelvic floor"[MeSH Terms] OR ("pelvic"[All Fields] AND "floor"[All Fields]) OR "pelvic floor"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

3. (("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("urinary incontinence"[MeSH Terms] OR ("urinary"[All Fields] AND "incontinence"[All Fields]) OR "urinary incontinence"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

4. (("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("urinary incontinence, stress"[MeSH Terms] OR ("urinary"[All Fields] AND "incontinence"[All Fields] AND "stress"[All Fields]) OR "stress urinary incontinence"[All Fields] OR ("stress"[All Fields] AND "urinary"[All Fields] AND "incontinence"[All Fields]))) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

5. ((("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("urinary bladder, overactive"[MeSH Terms] OR ("urinary"[All Fields] AND "bladder"[All Fields] AND "overactive"[All Fields]) OR "overactive urinary bladder"[All Fields] OR ("overactive"[All Fields] AND "bladder"[All Fields]) OR "overactive bladder"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

6. ((("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("exercise"[MeSH Terms] OR "exercise"[All Fields]) AND ("pelvic floor"[MeSH Terms] OR ("pelvic"[All Fields] AND "floor"[All Fields]) OR "pelvic floor"[All Fields]) AND ("muscles"[MeSH Terms] OR "muscles"[All Fields] OR "muscle"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

7. ((("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND neuromuscular[All Fields] AND ("electric stimulation"[MeSH Terms] OR ("electric"[All Fields] AND "stimulation"[All Fields]) OR "electric stimulation"[All Fields] OR ("electrical"[All Fields] AND "stimulation"[All Fields]) OR "electrical stimulation"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

8. (#6) AND #4 AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial [ptyp])

9. (#6) AND #3 AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial [ptyp])

10. (#7) AND #3 AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial [ptyp])

11. ((("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("faecal incontinence"[All Fields] OR "fecal incontinence"[MeSH Terms] OR ("fecal"[All Fields] AND "incontinence"[All Fields]) OR "fecal incontinence"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial [ptyp])

12. ((("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND anal[All Fields] AND ("urinary incontinence"[MeSH Terms] OR ("urinary"[All Fields] AND "incontinence"[All Fields]) OR "urinary incontinence"[All Fields] OR "incontinence"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized

13. ((("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("sexual behavior"[MeSH Terms] OR ("sexual"[All Fields] AND "behavior"[All Fields]) OR "sexual behavior"[All Fields] OR "sexual"[All Fields]) AND ("physiopathology"[Subheading] OR "physiopathology"[All Fields] OR "dysfunction"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

14. ((("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("dyspareunia"[MeSH Terms] OR "dyspareunia"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

15. ((("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("constipation"[MeSH Terms] OR "constipation"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

16. ((("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("intestines"[MeSH Terms] OR "intestines"[All Fields] OR "intestinal"[All Fields]) AND ("constipation"[MeSH Terms] OR "constipation"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

17. ((("biofeedback, psychology"[MeSH Terms] OR ("biofeedback"[All Fields] AND "psychology"[All Fields]) OR "psychology biofeedback"[All Fields] OR "biofeedback"[All Fields]) AND ("pelvic floor"[MeSH Terms] OR ("pelvic"[All Fields] AND "floor"[All Fields]) OR "pelvic floor"[All Fields]) AND ("muscles"[MeSH Terms] OR "muscles"[All Fields] OR "muscle"[All Fields]) AND ("physiopathology"[Subheading] OR "physiopathology"[All Fields] OR "dysfunction"[All Fields])) AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial[ptyp])

18. (#14) AND #6 AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial [ptyp])

19. (#15) AND #6 AND ("humans"[MeSH Terms] AND "female"[MeSH Terms] AND Randomized Controlled Trial [ptyp])

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