Pelvic Floor Physical Therapy for Pelvic Floor Hypertonicity: A Systematic Review of Treatment Efficacy

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ABSTRACT

Introduction: Hypertonicity of the pelvic floor (PFH) is a disabling condition with urological, gynecological and gastrointestinal symptoms, sexual problems and chronic pelvic pain, impacting quality of life. Pelvic floor physical therapy (PFPT) is a first-line intervention, yet no systematic review on the efficacy of PFPT for the treatment of PFH has been conducted.

Objectives: To systematically appraise the current literature on efficacy of PFPT modalities related to PFH.

Methods: PubMed, Embase, Emcare, Web of Science, and Cochrane databases were searched from inception until February 2020. A manual search from reference lists of included articles was performed. Ongoing trials were reviewed using clinicaltrial.gov. Randomized controlled trials (RCTs), prospective - and retrospective cohorts and case-study analyses were included.

Outcome measures were pelvic floor muscle tone and function, pain reports, sexual function, pelvic floor symptom scores, quality of life and patients' perceived effect.

Results: The literature search resulted in 10 eligible studies including 4 RCTs, 5 prospective studies, and 1 case study published between 2000 and 2019. Most studies had a high risk of bias associated with the lack of a comparison group, insufficient sample sizes and non-standardized interventions. Six studies were of low and 4 of medium quality. All studies were narratively reviewed. Three of 4 RCTs found positive effects of PFPT compared to controls on five out of 6 outcome measures. The prospective studies found significant improvements in all outcome measures that were assessed. PFPT seems to be efficacious in patients with chronic prostatitis, chronic pelvic pain syndrome, vulvodynia, and dyspareunia. Smallest effects were seen in patients with interstitial cystitis and painful bladder syndrome.

Conclusion: The findings of this systematic review suggest that PFPT can be beneficial in patients with PFH. Further high-quality RCTs should be performed to confirm the effectiveness of PFPT in the treatment of PFH.

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Key Words: Pelvic Floor; Hypertonicity; Overactivity; Pelvic Floor Physical Therapy; Physiotherapy

INTRODUCTION

The pelvic floor (PF) is a multifunctional complex of muscle fibers, fascia, ligaments, and connective tissue that form a hammock at the bottom of the abdomino-pelvic cavity. The muscles of the PF consist of superficial muscles including the m. bulbospongiosus, m. ischiocavernosus, the perineal muscles, and external anal sphincter muscle. The deep PF muscles are the levator ani composed of the puborectalis, pubococcygeus, and iliococcygeus. The PF provides anatomical support for the pelvic and abdominal viscera and is involved in urinary, defecatory, and sexual function.[1–4] The PF is capable of generating and controlling intra-abdominal pressure together with other muscles surrounding the abdominal cavity and contributes to lumbar spine stiffness.[5,6]

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Pelvic floor hypertonicity (PFH) is often associated with urological, gynecological, gastrointestinal and sexual problems as well as chronic pelvic pain. Prevalence ranges from 50% to 90%.[7,8] These complaints have a profound impact on quality of life.[9–12] Several terms are used for PFH in the literature, such as pelvic floor spasm, nonrelaxing pelvic floor and overactivity. Currently, the International Urogynecological Association (IUGA)/International Continence Society (ICS) defines the term "non-neurogenic hypertonicity" as an increase in muscle tone related to the contractile or viscoelastic components that can be associated with either elevated contractile activity and/or passive stiffness in the muscle.[13] In addition, the hypertonic muscle tissue may contain myofascial trigger points (MTrPs).[14] A MTrP is a discrete, hyperirritable nodule in a taut band of a skeletal muscle which is palpable and tender during physical examination. An active MTrP is clinically associated with spontaneous pain in the surrounding tissue and/or to distant sites in specific referred pain patterns.[15,16]

PFH can be a primary problem or a secondary adaptation to an acute or chronic injury to one or more musculoskeletal components in the PF and surrounding structures. Pelvic surgery, traumatic vaginal delivery, traumatic injury of the back or pelvis, gait disturbances, pelvic pain, experienced threat, and (chronic) stress are found to be associated with PFH.[17–20] PFH is assumed to be related to learned behavior, otherwise acquired in adulthood through voluntary holding to inhibit micturition or defecation or to avoid incontinence. This might be related to habit, lifestyle, and/or stressful occupation.[9] A history of physical or sexual abuse or insecure attachment is common among women with PFH and is associated with impaired sexual arousal, desire, and orgasm.[21,22] Laan et al.[23] conceptualized PFH as a symptom of chronic activation of the defensive stress-system, and should thus be regarded as a physical manifestation of emotional dysregulation.

Clinically, PFH is diagnosed by digital palpation of the PF. This includes assessment of muscle tone (resistance provided by a muscle when a pressure/deformation or a stretch is applied to it) and muscle function (voluntary contractility, strength, endurance, repeatability, co-contraction, and relaxation ability).[8,13,24,25] There is no single accepted or standardized way of measuring muscle tone and there are no normative values.[13] Digital palpation can be combined with the use of surface electromyography (s-EMG) and dynamometry.[8,26] To access pain and MTrPs, patient-reported outcome measures can be used and include numerical rating scales (NRS), visual analog scales (VAS),[27,28] and simple verbal pain rating scales.[13]

Pelvic floor physical therapy (PFPT) is considered to be an important part of treatment of PFH and includes strategies to optimize lumbopelvic, spinal and PF muscle function and to improve urinary, defecatory, and sexual function.[29–31] The aim of PFPT is to increase awareness and proprioception, to improve muscle relaxation and elasticity of the PF and to reduce pain. Interventions consist of education about the PF and related symptoms, behavioral modifications, exercises aimed at PF awareness and relaxation combined with soft-tissue manipulation and myofascial release.[30,32–35] Another frequently used treatment modality is s-EMG to register PF muscle activation with intravaginal or-anal electrode probes.[36,37] Electro galvanic stimulation is used to improve muscle proprioception and relaxation of the PF muscles and is used as form of neuromodulation for pain relief.[38–41] To date, efficacy of this range of treatments is not yet well established. Investigation by systematically reviewing the effectiveness of PFPT for PFH as a stand-alone entity has not yet been performed.

The goal of this review was to systematically appraise the current literature on the effectiveness of PFPT for the treatment of PFH.

METHODS

Search strategy

This systematic review adhered to guidelines detailed in the Preferred reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement.[42]

A comprehensive literature search was conducted using the following electronic databases: MEDLINE, Embase, Emcare, and the Cochrane Central Register of Controlled Trials (Wiley Interface, current issue) from inception until February 2020. Protocol registry (http://www.clinicaltrials.gov) was screened for upcoming trials. The search strategy was developed by a health science librarian with experience in systematic review searching. Different relevant search terms (thesaurus terms and terms in title, abstract, or both) concerning PFH and PFPT were used. The following medical subject headings and text words were used: hypertonicity of the pelvic floor, overactive pelvic floor, non-relaxing pelvic floor, micturition disorder, defecation disorder, sexual dysfunction, chronic pelvic pain, physical therapy, myofeedback, and electrogalvanic stimulation. The reference lists of eligible studies and relevant systematic reviews were searched for additional articles that were not found in the main search. Search strings are listed in Appendix 1.

Inclusion and exclusion criteria

Randomized control trials (RCTs), cross-over studies, prospective and retrospective cohort studies and case studies involving PFPT in patients with PFH were included in the review. Inclusion criteria were: men and/or women (>18 years) with PF problems and complaints suggestive of PFH; muscle tone diagnosed by palpation and/or s-EMG; adequate description of the intervention. Studies with the following outcome measures were eligible: PF muscle tone, pain, sexual function, quality of life, PF symptoms and patients' perceived effect. Studies had to be original, available as full-text and written in English. Studies with patients with neurological diseases, low PF muscle tone, medication, surgery, sacral neuromodulation, and percutaneous tibial nerve stimulation were excluded.

Data collection and analysis

Two authors independently selected studies by screening titles and abstracts followed by full text screening. Any discrepancies

were resolved by discussion until consensus. The following data were extracted: first author, year of publication, country, inclusion and exclusion criteria, sample size, participants characteristics (such as age, gender, sample size), study design, details of the pelvic floor interventions, outcomes measurements and outcome. Level of bias was assessed using the Cochrane Collaboration's Risk of Bias criteria. For each of these risk domains, studies were categorized as at low, uncertain or high risk of bias based on random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other bias.[43]

Outcome measures

Alle outcome measures of included studies are listed in Table 1.

Treatments

The duration of treatment varied between 5 and 12 sessions, with sessions lasting between 30-75 minutes, over a period varying from 5 days to 3 months. PFPT protocols in the studies consisted of at least 3 of the following interventions: education about anatomy and function of the PF and related symptoms[44–47]; digital vaginal palpation of the PF for proprioception and to guide home exercises[46,48]; manual techniques to release MTrPs of the PF and soft-tissue massage, including stretching, external manipulation of the PF and surrounding muscles[35,45,46,48–52]; insertion techniques using dilatators[45]; muscle exercises focused on awareness and relaxation[35,44,46,48,49,51,52]; infrared thermotherapy[48]; home exercises[35,45–49,51,52] and bladder training.[47] Four studies used s-EMG[44,45,47,48] and 2 studies used electrogalvanic stimulation.[45,46] Treatment in the control-arm of the 4 RCTs consisted of no-treatment[46]; western massage of lower back

Table 1. Outcome measures

Muscle tone and function	○ Modified Oxford-scale[50] ○ 7-point digital palpation scale muscle tone (−3 to +3)[45] ○ 4-point digital palpation score for muscle flexibility and muscle relaxation (0–4)[45] ○ Vulvalgesiometer[45] ○ Rest s-EMG-values[44,45,48] ○ Modified Oxford-scale function[45,46] ○ The New PERFECT-scale[48]
Pain	○ Digital palpation of the pelvic floor muscles (levator, obturator internus, diaphragm urogenital)[51] ○ Visual analog scales (VAS)[35,46,47,49] ○ The National Institutes of Health-Chronic Prostatitis Symptom Index (NIH-CPSI)[35,44,49,51] ○ Pelvic pain symptom scale (PPSS)[35,49] ○ Likert visual analog scale[50-52] ○ VAS-scores to assess vulvar pain[45] ○ Degree of pain during sexual intercourse[48]
Sexual Function	○ Female Sexual Function Index (FSFI)[46,48,51,52] ○ Cervantes scale measuring sexual response cycle on Quality of Life (QoL)[48] ○ Sexual health domain of the PPSS[35,49] ○ Sexual Health Inventory for Men (SHIM)[51]
Pelvic floor symptoms	○ O'Leary-Sant IC Symptom/Problem Index (ICSI/ICPI)[50–52] ○ NIH-CPSI[35,44,49,51] ○ American Urological Association (AUA) symptom and bother score[47] ○ VAS-urgency/VAS-voiding frequency[47] ○ Likert visual analog scale urgency[50,52] ○ Likert visual analog scale frequency[52] ○ Pelvic pain symptom scale (PPSS)[35,49]
Quality of life	○ Cervantes QoL[48] ○ VAS-QoL[45] ○ NIH-CPSI domain QoL[35,44,49,51] ○ 12-item Short Form survey (SF-12)[50–52]
Patient's' perceived effect	○ Global Response Assessment (GRA)[35,49,51,52]

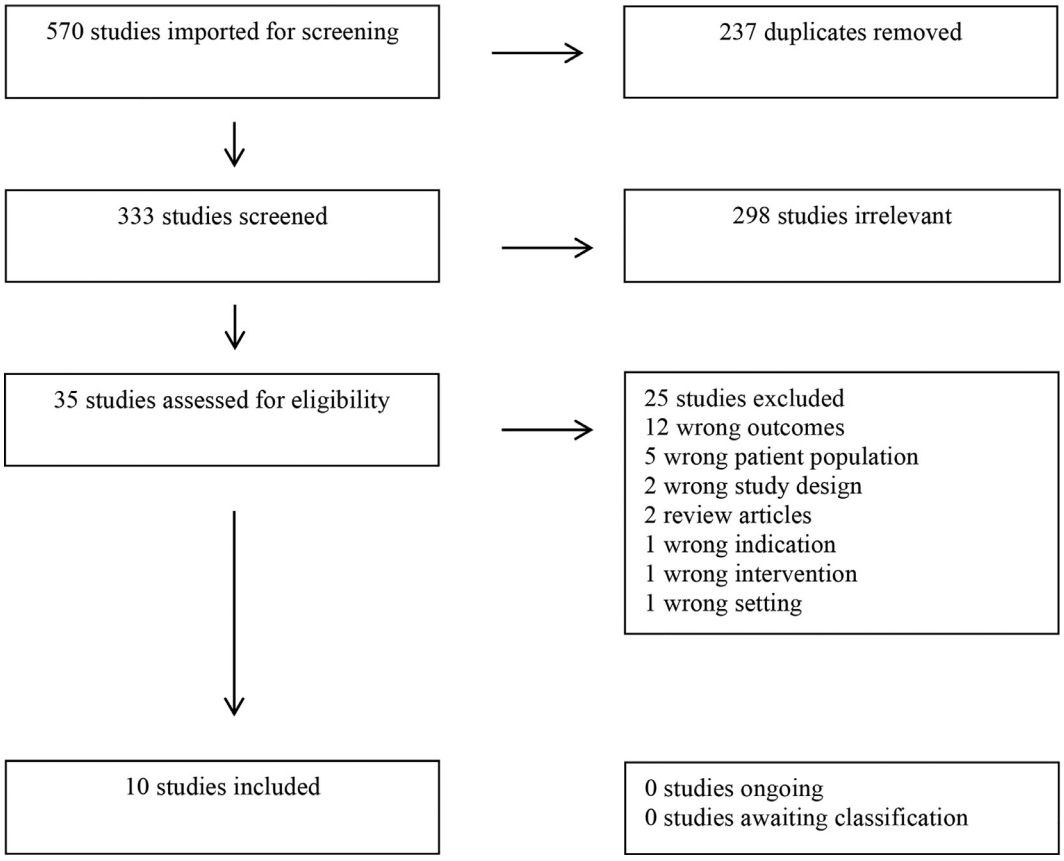

Figure 1. PRISMA flowchart.

muscles[51,52]; heat applied to lower back and myofascial release of the abdominal diaphragm, piriformis, and iliopsoas muscles.[48]

RESULTS

Search results

In total, 570 studies were identified through electronic searches of which 237 duplicates were removed. Of the remaining 333 studies, 298 were excluded based on title and abstract screening. Thirty-five references were read in full, after which 25 references were excluded (see Figure 1 for exclusion reasons). A total of 10 studies met the inclusion criteria. Four studies were RCTs,[46,48,51,52], there was one case study[35] and 5 prospective cohort studies.[44,45,47,49,50] No ongoing studies were found. Studies represented a total of 581 participants, samples sizes in the studies varied from 19 to 138 patients. Patients with sexual problems were investigated in 2 RCTs[46,48] and in one prospective cohort study.[45] These studies involved patients with dyspareunia and provoked vestibulodynia (PVD). Patients with interstitial cystitis and painful bladder syndrome (IC/PBS) were investigated in 2 RCTs[51,52] and 1 prospective study.[50] Patients with chronic prostatitis and chronic pelvic pain syndrome (CP/CPPS) were studied in one RCT,[51] 3 prospective studies[44,47,49] and in the case study.[35] Given the marked heterogeneity of the studies, with different indications, outcome measurements and interventions, all studies were narratively reviewed.

Study quality assessment

A summary of study design, patient characteristics, sample size, interventions, outcome assessments and findings are listed in Table 2.

The quality assessment (see Figure 2) related to selection bias indicated a high risk of bias for six studies due to the absence of randomization or a comparison group. Blinding of participants and personnel for treatment received was feasible in none of the studies. Blinding of outcome assessment was at high risk in 8 studies.[35,44–48,50,51] Attrition bias (dropout) was high in 3 studies.[35,47,50] Risk of reporting bias was high due to insufficient information about the exact treatment protocol in 2 studies,[35,50] and high due to insufficient information about interpretation of the results.[52] Eight of the 10 studies described their treatment protocols in detail.[44–49,51,52] Sample-size calculation was reported in the 4 RCTs.[46,48,51,52] Other risks of bias concerned loss of funding or insurance to complete the study. We considered 6 studies to be of low quality, with only 0–2 low bias risks.[35,44,45,47,49,50] The other 4 studies were of medium quality.[46,48,51,52]

Table 2. Study characteristics of the included studies

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
Fitzgerald et al. (2009)	RCT N = 47	Women and men with IC/ PBS and CP/CPPS PFPT: 41.1(11.4) Controls: 44.9(14.0)	PFPT Internal (pelvic) and external MTrP and connective tissue manipulation PF, hip girdle and abdomen Neuromuscular education Proprioceptive awareness exercises/ home exercises	PF digital palpation tenderness/ pain	Pre- to post-treatment: IC/PBS ($P < .001$) CP/CPPS ($P < .001$) PFPT vs control: IC/PBS ($P < .05$) CP/CPPS ns
			Control Full body Western massage	Likert pelvic pain	Pre- to post-treatment: IC/PBS ($P < .01$) CP/CPPS ($P < .001$) PFPT vs control: IC/PBS ns CP/CPPS ns
			10 weekly 1-hour sessions	NIH-pain	Pre- to post-treatment: CP/CPPS ($P < .001$) PFPT vs control ns
				SHIM	Pre- to post-treatment:ns PFPT vs control:ns
				FSFI	Pre-post treatment: IC/PBS ($P < .01$) PFPT vs control:ns
				ICSI	Pre- to post-treatment: IC/PBS ($P < .05$) CP/CPPS ($P < .01$) PFPT vs control: IC/PBS ($P < .05$) CP/CPPS ns
				ICPI	Pre- to post-treatment: IC/PBS ($P < .01$) CP/CPPS ($P < .01$) PFPT vs control:

(continued)

Table 2. Continued

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
					IC/PBS ($P < .05$) CP/CPPS ns
				NIH-CPSI total	Pre- to post-treatment: CP/CPPS ($P < .001$) PFPT vs control:ns
				NIH-urinary	Pre- to post-treatment: CP/CPPS ($P < .001$) PFPT vs control ($P < .01$)
				NIH- QoL	Pre- to post-treatment: CP/CPPS ($P < .05$) PFPT vs control ns
				Likert urinary urgency score	Pre- to post-treatment: IC/PBS ($P < .01$) PFPT vs control ns
				Likert urinary frequency score	Pre- to post-treatment: IC/PBS ($P < .05$) PFPT vs control ns
				SF-12 physical scale	Pre- to post-treatment: IC/PBS ns CP/CPPS ($P < .05$) PFPT vs control: IC/PBS ns CP/CPPS ns
				SF-12 mental scale	Pre- to post-treatment: IC/PBS ns CP/CPPS ns PFPT vs control: IC/PBS ns CP/CPPS ns

(continued)

Table 2. Continued

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
				GRA	PFPT vs control: IC/PBS (P< .05) CP/CPPS ns
Schvartz-man et al. (2019)	RCT N=42	Pre- and postmenopausal women with dyspareunia PFPT: 51.9 (5.3) Controls: 50.6 (4.7)	PFPT PF digital palpation using NEW PERFECT scale Myofascial release PF PF infrared thermotherapy Hold/relax exercises Myofascial release of abdominal diaphragm, piriformis and iliopsoas S-EMG biofeedback training	New PERFECT scale	Pre- to post-treatment: P-mean (P< 0001) E-mean (P< .001) R-mean (P< .001) F-mean (P< .001) E-mean: NA C-mean (P≤ .001) T-mean ns PFPT vs control: P-mean (P < 005) E-mean (P< .005) R-mean (P< .05) F-mean (P< .01) E-mean: NA C-mean (P< .001) T-mean: (P< .05)
			Control Heat applied to lower back and myofascial release of abdominal diaphragm, m. piriformis, m. iliopsoas	S-EMG resting tone (uV) S-EMG sustained contraction duration	Pre- to post-treatment ns PFPT vs control ns Pre- to post-treatment ns PFPT vs control (P< .05)
			7 one-hour sessions	VAS pain during sexual intercourse	Pre- to post-treatment P< .001 PFPT vs control P< .001
				FSFI	Pre- to post-treatment: Desire (P< .05) Arousal (P< .05) Lubrication (P< .05) Orgasm (P< .001) Satisfaction (P < .001) Pain (P < .001) Total Score (P < .001)

(continued)

Table 2. Continued

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
					PFPT vs control: Desire ns Arousal ns Lubrication ($P < .05$) Orgasm ns Satisfaction ns Pain ($P < .05$) Total Score: ns
				Cervantes QoL	Pre-to posttreatment: Menopause Health ($P < .001$) Sexuality ($P < .001$) Couple relationship ns Physical ns Total Score ($P < .001$) PFPT vs control: Menopause Health ns Sexuality ns Couple relationship ns Physical ns Total Score ns
Ghaderi et al.(2019)	RCT N=64	Premenopausal women with dyspareunia PFPT: 34.9 (9.2) Controls: 35.7 (8.0)	PFPT Explanation of pelvic anatomy and function PF digital palpation proprioception Manual techniques PF Intravaginal EGS (110Hz, 80ms) PF home exercises	Modified Oxford -scale	PFPT vs control: PF muscle strength: ($P < .001$) PF muscle endurance ($P < .05$)

(continued)

Table 2. Continued

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
			Control No treatment	VAS pain	PFPT vs control: ($P < .05$) Significant difference remains at 3-months follow-up
			10 sessions in 3 months	FSFI	PFPT vs control: Desire ($P < .05$) Arousal ($P < .05$) Lubrication ($P < .05$) Orgasm ($P < .05$) Satisfaction ($P < .05$) Pain ($P < .05$) Total Score ($P < .05$)
Fitzgerald et al. (2012)	RCT N=81	Women with IC/PBS PFPT: 43.1 (15.1) Controls: 43.0 (12.9)	PFPT Internal(pelvic) and external MTrP and connective tissue manipulation PF, hip girdle and abdomen Neuromuscular education Proprioceptive awareness exercises/ home exercises	Likert bladder pain score	PFPT vs controls ns
			Control Full body global therapeutic massage	FSFI Total Score	PFPT vs controls ns
			10 weekly 1-hour sessions	ICSI ICPI	PFPT vs controls ns PFPT vs controls ns
				Likert urgency score Likert frequency score	PFPT vs controls ns PFPT vs controls ns
				SF-12 physical scale SF-12 mental scale	PFPT vs control ns PFPT vs control ns
				GRA	PFPT vs control ($P < .005$)

(continued)

Table 2. Continued

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
Gentilcore —Saulnier et al. (2010)	Prospective cohort study N=22	Women with and without PVD PFPT: 22.0 (2.0) Controls: 21.0 (1.0)	PFPT Explanation of pelvic anatomy and function Digital intravaginal techniques Insertion techniques using dilatators S-EMG- biofeedback training and EGS (15Hz,250msec) PF home exercises and dilator insertion	Vaginal palpation general tone	Pre-treatment group difference (p<005) Post-treatment group difference ns PFPT pre-posttreatment ($P < .01$)
			Control No treatment	Vaginal palpation flexibility at the vaginal opening	Pre-treatment group difference ($P < .01$) Post-treatment group difference ns PFPT pre-posttreatment ($P < .01$)
			8 one -hour treatments in 12 weeks	Vaginal palpation relaxation capacity after contraction	Pre-treatment group difference ($P < .05$) Post-treatment group difference ns PFPT pre-posttreatment ($P < .05$)
				Vaginal palpation strength	Pre-treatment group difference ns Post-treatment group difference ns PFPT pre-posttreatment ($P < .05$)

(continued)

Table 2. Continued

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
				S-EMG PFM tonic activity at rest	
				Deep PF muscles	Pre-treatment group difference ns
					Post-treatment group difference ns
					PFPT pre-posttreatment ns
				Superficial PF muscles	
					Pre-treatment group difference ($P < .05$)
					Post-treatment group difference ns
					PFPT pre-posttreatment ns
				S-EMG PF maximum voluntary contractile activity	Pre-treatment group difference ns
					Post-treatment group difference ns
					PFPT pre-posttreatment ns
				S-EMG At rest and during painful pressure stimulus	Pre-treatment group difference ($P < .005$)
					Post-treatment group difference ns
					PFPT pre-posttreatment ($P < .01$)

(continued)

Table 2. Continued

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
				S-EMG PF pain responses	
				Deep PF muscles	Pre-treatment group difference ns
					Post-treatment group difference ns
				Superficial PF muscles	PFPT pre-posttreatment ns
					Pre-treatment group difference ($P < .05$)
					Post-treatment group difference ns
					PFPT pre-posttreatment ($P < .0001$)
				Pain intensity	Pre-treatment group difference ($P < .01$)
					Post-treatment group difference ns
					PFPT pre-posttreatment ($P < .01$)
				Pain unpleasantness	Pre-treatment group difference ns
					Post-treatment group difference ns
					PFPT pre-posttreatment ($P < .001$)
				QoL	PFPT pre-posttreatment ($P < .01$)

(continued)

Table 2. Continued

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
Oyama et al. (2004)	Prospective pilot study N = 21	Women with IC PFPT: 42 (21–64)	PFPT Intravaginal massage and MTrP-release No control group	Modified Oxford scale muscle tone m iliococcygeus m pubococcygeus m obturator internus m coccygeus	 Pre- to post-treatment ($P < .05$) Pre- to post-treatment ($P < .05$) Pre-to posttreatment ($P < .05$) Pre- to post-treatment ns
			10 sessions for period of 5 weeks	Likert pain	Pre- to post-treatment ($P< .01$) Pretreatment-to follow-up ($P < .01$)
				Likert urgency	Pre- to post-treatment ($P < .001$) Pre-treatment- to follow-up ($P < .005$)
				ICPI	Pre- to post-treatment ($P < .05$) Pre-treatment- to follow-up ($P < .05$)
				ICSI	Pre- to post-treatment ($P < .05$) Pre-treatment-to follow-up ($p< 0.05$)
				SF-12 physical scale SF-12 mental scale	Pre- to post-treatment ($P < .05$) Pre-treatment-to follow-up ns Pre- to post-treatment ($P < .05$) Pre-treatment-to follow-up ns

(continued)

Table 2. Continued

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
Cornel et al. (2005)	Prospective cohort study N = 31	Men with CP/CPPS PFPT: 43.9 (23–70)	PFPT Explanation of pelvic anatomy and function s-EMG biofeedback training PF exercises	s-EMG rest uV	Pre- to post treatment ($P < .001$)
			No control group	NIH-CPSI pain	Pre-to post treatment ($P < .001$)
			6–8 sessions initially once a week later on every 2–4 weeks	NIH-CPSI micturition	Pre- to post treatment ($P < .001$)
				NIH-CPSI total	Pre- to post treatment ($P < .001$)
				NIH-CPSI QoL	Pre- to post treatment ($P < .001$)
Clemens et al. (2000)	Prospective cohort study N = 19	Men with CP/CPPS PFPT: 36 (18–67)	PFPT Explanation of pelvic anatomy and function s-EMG biofeedback training Bladder training Hold/relax PF home exercises	VAS pain score	Pre- to post treatment ($P < .001$)
				AUA bother score	Pre- to post treatment ($P < .001$)
			No control group	AUA symptom score	Pre-to post treatment ($P < .001$)
			6 biweekly 1-hour sessions	VAS urgency	Pre-to post treatment ($P < .005$)
				VAS voiding frequency	Pre-to post treatment ($P < .005$)
Anderson et al. (2011)	Prospective cohort study N = 116	Men with CP/CPPS PFPT: 48 (19–80)	PFPT Internal manual techniques PF home exercises Psychologist daily instructions on reducing nervous system	VAS pelvic pain	Pre-to post treatment ($P < .001$)

(continued)

Table 2. Continued

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
			No control group	PPSS sexuality	Pre-to post treatment ($P < .001$)
				PPSS symptom severity	Pre-to post treatment ($P < .001$)
			5 (30 to 60 min) sessions for 6 days	NIH-CPSI Total Score	Pre-to post treatment ($P < .001$) Pretreatment-to follow up ($P < .001$)
				NIH-CPSI QoL	Pre-to post treatment ($P < .001$)
				GRA	59% of patients reported symptoms as moderately or markedly improved
Anderson et al.(2005)	Case study N = 138	Men with CP/CPPS PFPT: 40.5 (16–79)	PFPT Internal manual techniques Deep tissue mobilisation Relaxation exercises Daily PF home relaxation exercises	VAS-pelvic pain	Pre- to post treatment: Markedly improved group ($P < .01$) Moderately improved group ns
			No control group	PPSS pain	Pre- to post treatment: Markedly improved group ($P < .001$) Moderately improved group ns
			8 biweekly sessions and 4 weekly sessions	NIH CPSI pain	Pre- to post treatment: Markedly improved group ($P < .001$) Moderately improved group ($P < .05$)
				PPSS sexual function	63% of the patients had a 25% or greater improvement in sexual function; 56 (43%) achieved a 50% or greater response after PFPT

(continued)

Table 2. Continued

Study	Design/N	Population/ mean age SD/ range)	Interventions/duration	Outcome Measures (muscle tone/ function, pain, sexual function, pelvic floor symptoms, QoL, PPE)	Results
				PPSS urinary symptoms	Pre- to post treatment: Markedly improved group ($P < .001$) Moderately improved group ns
				NIH-CPSI Total score	Pre- to post treatment: Markedly improved group ($P < .001$) Moderately improved group ($P < .01$)
				NIH-CPSI urinary symptoms	Markedly improved group ($P < .05$)
				NIH-CPSI QoL	Moderately improved group ns
					Markedly improved group ($P < .001$) Moderately improved group ($P < .05$)

AUA = American Urological Association Symptom and Bother Score; CP/CPPS = Chronic Prostatitis/Chronic Pelvic Pain Syndrome; EGS = Electrogalvanic Stimulation; FSFI = Female Sexual Function Index; GRA = Global Response Assessment; IC/PBS=Interstitial Cystitis/Painful Bladder Syndrome; ICPI = Interstitial Cystitis Problem Index; ICSI = Interstitial Cystitis Symptom Index; MTrP = Myofascial Trigger Point; MVC = Maximum Voluntary Contraction; NA = not applicable; NEW-PERFECT = Performance/Endurance/Repetition/Fast/Elevation/Co-contraction/Timing; NIH/CPSI = National Institute of Health Chronic Prostatitis Symptom Index; PFPT = Pelvic Floor Physiotherapy; PPE = patient's perceived effect; PF = pelvic floor; PPSS = Pelvic Pain Symptom Scale; PVD = Provoked Vulvodynia; QoL = Quality of Life; RCT = Randomized Controlled Trial; SF-12 = 12-item Short Form Survey; SHIM = Sexual Health Inventory for Men; s-EMG = surface Electromyography; TENS = Transcutaneous Electro Neuro Stimulation; VAS = Visual Analogue Scale.
Note. Ns = non-significant.

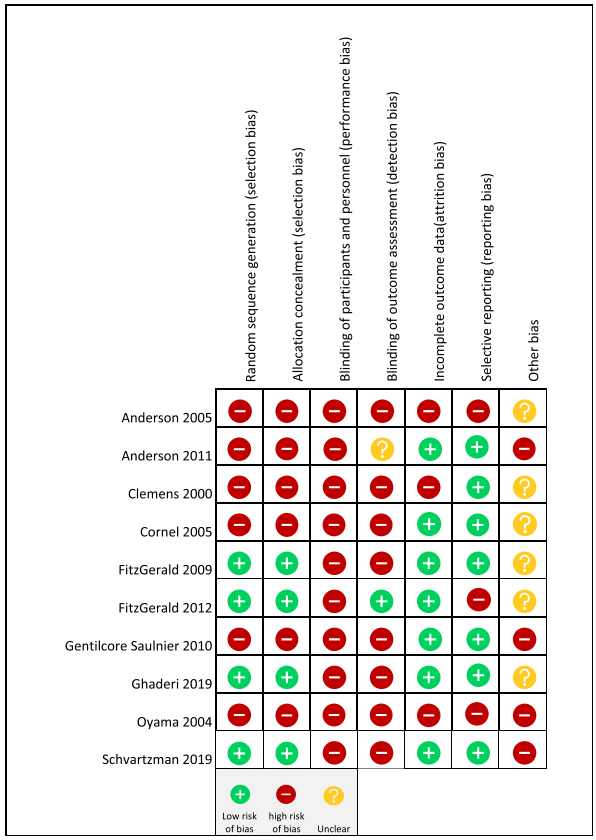

Figure 2. Risk of bias assessment.

Outcome assessments

Pelvic floor muscle resting tone and function. Changes in muscle tone as a result of PFPT were directly measured in one RCT[48] and in three prospective cohort studies.[44,45,50] The RCT[48] involved patients with dyspareunia and found that PFPT did not significantly decrease resting activity from baseline to post-treatment using s-EMG. In 1 prospective study[44] in men with CPPS, the mean value of the muscle tone measured with s-EMG decreased significantly from pre- to post-treatment. The second prospective cohort study[45] in women with PVD found a significant reduction in muscle tone, measured with the 7-point digital palpation scale, a significant increase from pre- to post-treatment in PF muscle flexibility and in the ability to relax the PF muscles after contraction measured with 4-point digital palpation scale. S-EMG demonstrated a higher tonic rest activity at pre-treatment in the superficial layer of PF muscles in the patient group compared to controls but not in the deeper layer of the PF muscles. The last prospective study[50] in women with IC showed significant improvement in muscle tone after PFPT in all PF muscles except for the coccygeus, using the modified Oxford Scale.

PF muscle function was measured in 2 RCTs[46,48] and 1 prospective study.[45] One RCT[48] involving patients with dyspareunia found that PFPT significantly increased sustained contractions from baseline to post-treatment and the number of peaks were significantly higher in the PFPT-group using s-EMG and compared to control who received heat applied to lower back and myofascial release of the abdominal diaphragm, piriformis, and iliopsoas muscle. A significant improvement was found in post-treatment PF muscle function measured with New-PERFECT scores in the PFPT- group and relative to baseline. The second RCT[46] involved patients with dyspareunia and found significant improvement in PF muscle strength and endurance in the PFPT group in comparison with a no-treatment control group using the modified Oxford-scale. One prospective cohort study[45] found a significant increase in PF muscle strength from pre- to post-treatment but not compared to control measured with the modified Oxford scale.

Pain. Pain scores were assessed in all studies. In 1 RCT[51] in patients with CP/CPPS and IC/PBS, PFPT resulted in significant relief of tenderness/pain in 4 muscle groups (levator ani posterior and anterior, obturator internus, and urogenital diaphragm) from pre- to post-treatment in both groups measured with digital examination. In the IC/PBS group a significant relief of tenderness/pain was found compared to controls who received full body global therapeutic massage. This study also found reduced pain scores measured with Likert pelvic pain score to be significantly reduced from pre- to post-treatment in both groups but not compared to controls. The second RCT[48] found a significant reduction in post-treatment dyspareunia pain scores using VAS in the PFPT group relative to controls. The third RCT[46] found post-treatment VAS pain scores in the genital area before, during, and after vaginal intercourse to be significantly decreased compared to no-treatment controls, which sustained after follow-up of three months. Only 1 RCT[52] was unable to show a decrease in pelvic/bladder discomfort and/or pain after PFPT compared to controls who received full body global therapeutic massage. One prospective study[50] in women with IC, found a significant decrease in pelvic pain measured with Likert scores compared to baseline. The second prospective cohort study,[45] in women with PVD demonstrated significant reduce of pain in the superficial PF muscles to a painful pressure stimulus induced with a vulvalgesiometer. Vulvar pain intensity ratings were also significantly decreased after treatment and no longer differed from non-affected controls. The third prospective study,[47] in men with CPPS, found significantly lower pelvic pain-scores after PFPT measured with VAS. The fourth prospective study[44] in men with CP/CPPS found a significant decrease in the subdomain pain of the National Institutes of Health-Chronic Prostatitis Symptom Index (NIH-CPSI) after PFPT. The fifth prospective study[49] in men with CP/CPPS also found significant improvement in pain from pre- to post-treatment in the subdomain of the NIH-CPSI and Pelvic Pain Symptom Scale (PPSS). Finally, the case study[35] demonstrated a more than 25% reduction in pelvic pain symptom scores using VAS-scores.

Sexual function. Sexual function was investigated in all 4 RCTs,[46,48,51,52] in one prospective study[49] and the case study.[35] One RCT[51] found significantly higher post-treatment Female Sexual Function Index (FSFI) total scores for women in the IC/PBS patient group compared to pre-treatment, no significant differences were found relative to control. In men with CP/CPSS, no significant differences in sexual function were found from pre- to post-treatment and relative to controls using the Sexual Health Inventory for Men. In the second RCT[52] no significant changes in FSFI total scores were observed from pre- to post-treatment, the same was true for controls. In the third RCT[46] in women with dyspareunia, the FSFI total scores were significantly improved after PFPT compared to no treatment controls. In the fourth RCT[48] in women with dyspareunia, the FSFI-scores improved significantly from pre- to post-treatment, FSFI-lubrication and pain improved significantly compared to controls. Cervantes QoL-sexuality improved significantly from pre- to post-treatment but not compared to controls. The prospective study[49] found significant improvement in sexual function measured with the sexual health domain of the PPSS. The case study[35] demonstrated an improvement in sexual function measured with PPSS of more than 50% in 51% of the patients after PFPT.

Improvement of pelvic floor symptoms. Symptom improvement was investigated in 2 RCTs,[51,52] 4 prospective studies[44,47,49,50] and the case study.[35] One RCT[51] found equal and significant improvement in urinary symptoms in the CP/CPSS group measured with the NIH-CPSI. Interstitial Cystitis Symptom Index/Interstitial Cystitis Problem (ICSI/ICPI) scores also showed improvement in urinary symptoms but only in the IC/PBS patient group. Another RCT[52] was unable to demonstrate a decrease in urgency and frequency ratings and ICSI/ICPI scores after PFPT. In a prospective study[49] in patients with CP/CPPS, NIH-CPSI total scores significantly decreased with approximately 30% after treatment. The second prospective study[44] in CP/CPPS patients showed significant symptom improvement in the subdomain NIH-CPSI-micturition. The third prospective study[47] found significant improvement in the American Urological Association Symptom and Bother Score and VAS urgency and VAS voiding frequency scores in patients with CP/CPPS. Significant improvement in symptoms measured with ICSI/ICPI was seen in the fourth prospective study[50] in patients with IC. At long-term follow-up, the improvement in ICPI and ICSI scores remained statistically significant. The case study[35] found that overall 72% of patients reported marked (46%) or moderate (26%) improvement after PFPT. Urinary symptoms decreased significantly in patients reporting marked improvements. More than half of the patients treated with PFPT had a 25% or greater decrease in urinary symptom scores, as assessed by the PPSS.

Quality of life. Quality of life was measured in 3 RCTs,[48,51,52] and 4 prospective studies[44,45,49,50] and the case study.[35] One RCT[48] in patients with dyspareunia found significant improvement in QoL from pre- to post-treatment but not compared to controls measured with the Cervantes scale. Another RCT[52] in IC/PBS patients found no significant improvement relative to controls in quality of life using the 12-item Short Form Survey (SF-12). In the RCT[51] with CP/CPPS and IC/PBS patients no differences were found between treatment groups in the QoL-domain of the SF-12, whereas a significant pre-post treatment improvement was found using both the SF-12 and NIH-CPSI, but in the CP/CPPS group only. One prospective study[45] found a significant decrease in the perceived negative impact of PVD on QoL measured with a VAS-scale. Two prospective studies[44,49] in men with CP/CPPS found a significant improvement in the NIH-CPSI subdomain QoL scores. Another prospective study[50] in women with IC showed significant improvements in the physical component summary score and mental component summary score of the SF-12. The case study[35] found significant improvement in quality of life domain of the NIH-CPSI after PFPT.

Patients' perceived effect. Patients' perceived effect was measured in 2 RCTs,[51,52] one prospective study[49] and the case study.[35] In a RCT[52] comparing PFPT with lower back massage, a significantly larger proportion of patients than controls reported having benefited from treatment (59% vs 26%, respectively). Likewise, another RCT[51] found a significantly larger proportion of patients (57%) reporting benefit relative to controls (21%). In one prospective study[49], 59% of the patients with CP/CPPS reported symptoms as moderately or markedly improved. In the case study,[35] 72% of patients had higher global response assessment scores indicating global improvement.

DISCUSSION

Three of 4 RCTs found positive effects of PFPT compared to controls on five of six outcome measurements (PF muscle resting tone and function, various features of pain, sexual function, PF symptoms, and patient's perceived effect). QoL remained unchanged in two of three RCTs. The 5 prospective studies found significant improvements from pre- to post-treatment on all of the outcome measures that they assessed (PF muscle resting tone and function in 3 studies; pain in all studies; sexual function in 1 study; PF symptoms in 4 studies, QoL in 4 studies and patients' perceived effect in 1 study). Finally, the case study found positive effects on all outcome measures that were assessed (pain, sexual function, symptoms, QoL, and patients' perceived effect). Taken together, the findings of this systematic review suggest that PFPT can be beneficial in patients with PFH. However, it should be noted that the RCT[52] with the largest sample size demonstrated an effect of PFPT in only 1 of 5 outcome measures, namely patients' perceived effect. This was 1 of 2 RCTs[51,52] that measured the least effect of PFPT in patients with IC/PBS. It is not entirely clear why this particular RCT

yielded negative results. Possibly, PFH in these patients is secondary to a visceral abnormality and therefore they may benefit less from PFPT than other PFH patient groups. The treatment modalities of PFPT used in this protocol may have been insufficient for this patient group, or perhaps the pain and urological complaints in this patient group was unrelated to PFH. This was also the study in which a substantial proportion of the participants (62%) reported at least one adverse event, the most common adverse event being pain in the bladder or pelvis. The high pain ratings may have negatively influenced the other outcome measurements. The other RCT[51] had post treatment data of only 11 participants with IC/PBS and should therefore be considered less reliable.

Treatment of PFPT proved to be most efficacious in improving muscle resting tone and function and pain. The five studies that measured muscle resting tone and function directly, all found significant improvements,[44–46,48,50] and for pain 9 of 10 studies found pain to significantly decrease with PFPT. Interestingly, the 2 RCTs[46,48] in women with dyspareunia found treatment effects in muscle function, a reduction in pain, as well as improvements in sexual function. Muscle function may be an important variable involved in sexual function. In an experimental study in women with PVD, Naess, and Bø[53] found maximal voluntary PF muscle contraction to reduce vaginal resting pressure and resting s-EMG activity. Their findings suggest that improving maximal voluntary PF muscle contractions are instrumental in treating PFH. In a study in patients with PVD[45] pain and muscle resting tone improved but unfortunately, sexual function was not investigated. Three studies[45,46,48] showed that PFPT decreased vulvar pain and pain during intercourse. These findings suggest that PFH is a maintaining factor in vulvar pain syndromes. Sexual function was also improved in patients who did not present with sexual problems as their primary complaint.[35,49]

QoL improved significantly in 6 of 8 studies,[35,44,45,48–50] but no improvement was seen in the 2 RCTs that measured QoL.[51,52] These were the RCTs in patients with IC/PBS, the majority of whom had high pain ratings during treatment. Possibly other contributing factors may be involved that affect their QoL, such as depression and anxiety as a consequence of chronic pain.[54] An outcome measure related to QoL, self-reported global perceived effect, improved significantly in all 4 studies that assessed this variable.[35,49,51,52] Surprisingly, the RCT[52] with the largest sample of IC/PBS patients did report greater global perceived effect than the controls. Even though their symptoms did not improve significantly, patients apparently did feel that the treatment was worthwhile. The authors of the study neither noted nor discussed this discrepancy. Other than a possible placebo effect, we have no explanation for this finding.

Several limitations of the studies in this systematic review impede the interpretation of the findings, such as the heterogeneity of patient groups and outcome measures, the small number of RCTs that met our inclusion criteria and the wide range of treatment modalities. In addition, an RCT is a prerequisite for preventing selection bias, performance bias, and detection bias which was a common limitation in most of the reviewed studies. Treatment programmes varied considerably in their content and duration and some data were incompletely reported. Most studies did not present follow-up data of adequate duration. In addition, none of the 10 studies were of high quality.

Although muscle resting tone improved in most studies that measured this, these findings should be interpreted with caution. Muscle resting tone was mostly quantified by digital palpation using various scales. These scales require a subjective interpretation on the part of the assessor and in some studies, the physical therapist providing the treatment was also the one assessing improvement. This may have biased the findings towards a positive outcome. In four studies muscle resting tone and function was established using more objective measures such as s-EMG,[44,45,47,48] but caution is warranted in clinical use and interpretation of this measure as well. Many factors influence amplitude, skin conductance and artefacts. Other common problems with s-EMG include a wide variation in equipment and electrodes, protocols and nonstandardized normal rest s-EMG values.[55] It would be advisable to use s-EMG measures in conjunction with other muscle resting tone measures.[13,48] Overall, it is clear that better outcome measures are needed. Another issue concerns the use of questionnaires. The wide range of conditions in which PFH seems to be involved as well as the wide range of PFH symptoms render the decision about which questionnaires to include in a study a difficult one. Only validated patient related outcome measures will bring this field further along.

CONCLUSION

The findings of this systematic review suggest that PFPT can be beneficial in patients with PFH. Given the low to moderate study quality, more high-quality RCTs with standardized treatment protocols, sufficient sample sizes, validated outcome measures, and long-term follow-ups should be performed to confirm the effectiveness of PFPT in the treatment of PFH.

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APPENDIX 1

Search strategy

((((("Pelvic floor"[ti] OR "Pelvic Diaphragm"[ti] OR "Pelvic Floor"[majr] OR "Pelvic Floor/physiopathology"[mesh] OR "Pelvic Floor Disorders"[majr] OR ("Practice Guideline"[ptyp] AND "pelvic"[ti]) OR "pelvic"[ti]) AND (Overactivity OR hypertonicity OR hypertonic OR hypertonic* OR tone OR tonicity OR tonic OR relaxation OR Non-relaxing OR Non-relaxing OR spasm OR spasms OR stiffness OR stiff OR contracture OR contracting OR cramp OR cramps OR cramp OR "levator ani"[tw] OR "levator ani syndrome" OR "levator syndrome"[tw] OR "muscle activity"[tw] OR "Practice Guideline"[ptyp] OR "tenderness"[tw])) OR "pelvic floor hypertonia" OR "pelvic floor hypertonicity" OR "pelvic floor hypertonus") AND (micturition OR micturit* OR defecation OR defaecation OR defecat* OR defaecat* OR sexual function OR sexual dysfunction OR sexual function* OR sexual dysfunction* OR prolapse OR prolaps* OR stress Urinary incontinence OR Urge urinary incontinence OR mixed incontinence OR incontinence OR incontin* OR overactive bladder OR urgency OR frequency OR obstructed micturition OR constipation OR constipat* OR dyssynergia OR dyssynerg* OR obstipation OR obstipat* OR vulvodinia OR vulvodynia OR vulvodin* OR vulvodyn* OR dyspareunia OR vaginism OR vaginismus OR vaginism* OR erectile dysfunction OR chronic testicular pain OR chronic pelvic pain OR chronic pelvic pain syndrome OR CPPS OR ejaculation OR premature ejaculation OR premature ejacul* OR Provoked vestibulodynia OR Dysfunctional voiding OR Voiding dysfunction OR Obstructed defaecation OR Obstructed defecation OR Coccygodynia OR Anal pain OR Chronic anal fissure OR Chronic anal fissures OR Proctalgia OR Ejaculation precox OR Ejaculation praecox OR Scrotal pain) NOT ((("Child"[mesh] OR "child"[ti] OR "children"[ti] OR "girl"[ti] OR "girls"[ti] OR "boy"[ti] OR "boys"[ti] OR pediatr*[ti] OR paediatr*[ti]) NOT ("Adult"[mesh] OR "adult"[ti] OR "adults"[ti])) OR "Pharmaceutical Preparations"[majr] OR "medication"[ti] OR "medications"[ti] OR "drug"[ti] OR "drugs"[ti] OR "Drug Therapy"[majr] OR pharmaco*[ti] OR "Botulinum Toxins"[majr] OR "Botulinum Toxins"[ti] OR "Botulinum Toxin"[ti] OR "botox"[ti] OR "Cholinergic Antagonists"[majr] OR "Cholinergic Antagonists"[ti] OR "Cholinergic Antagonist"[ti] OR anticholinergic*[ti] OR anti-cholinergic*[ti] OR (("Nervous System Diseases"[majr] OR "Nervous System Diseases"[ti] OR "Nervous System Disease"[ti] OR "neurological diseases"[ti] OR "neurological disease"[ti]) NOT ("Spasm"[majr] OR "spasm"[ti] OR "spasms"[ti])) OR (("Surgical Procedures, Operative"[majr] OR "surgery"[ti] OR surgical*[ti]) NOT "after"[ti]) OR "Implantable Neurostimulators"[majr] OR "Implantable Neurostimulators"[ti] OR "Implantable Neurostimulator"[ti] OR neuromodulat*[ti] OR rehabilitat*[ti] OR "Rehabilitation"[majr] OR "rehabilitation"[Subheading] OR "physical therapy modalities"[majr] OR "physical therapy"[ti] OR "physiotherapy"[ti] OR physiotherap*[ti] OR "exercise"[majr] OR "exercise"[ti] OR "exercises"[ti] OR "exercise therapy"[majr] OR "biofeedback, psychology"[majr] OR "biofeedback"[ti] OR "bio-feedback"[ti] OR bio-feedback*[ti] OR "myofeedback"[ti] OR myofeedback*[ti] OR "myo-feedback"[ti] OR myo-feedback*[ti] OR "electrostimulation"[ti] OR electrostimulat*[ti] OR "electric stimulation"[majr] OR "electric stimulation"[ti] OR "electrical stimulation"[ti] OR "life style"[majr] OR "life style"[ti] OR "lifestyle"[ti] OR "Conservative Treatment"[majr] OR "conservative management"[ti] OR "conservative treatment"[ti] OR "muscle therapy"[ti] OR "Electromyography"[majr] OR "electromyography"[ti] OR electromyogr*[ti] OR "EMG"[ti] OR "EMGs"[ti] OR "magnetic resonance imaging"[majr] OR "magnetic resonance"[ti] OR "Ultrasonography"[majr] OR ultrasoun*[ti] OR ultrason*[ti] OR "mapping"[ti]) AND english[la]) AND ("2009/01/01"[PDAT]: "3000/12/31"[PDAT])