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Review

Does evidence support physiotherapy management of adult female chronic pelvic pain? A systematic review

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ABSTRACT

Background and purpose: Chronic pelvic pain (CPP) is a debilitating condition among women with a major impact on health-related quality of life, work productivity and health care utilisation. The exact prevalence of chronic pelvic pain is not known, but 3.8% is commonly suggested. Musculoskeletal dysfunction is frequently cited as a possible aetiology. Physiotherapy is therefore recommended as one treatment modality. The aim of this systematic review was to source and critically evaluate the evidence for an effect of physiotherapy on pain, physical activity and quality of life in the treatment of female CPP.
Methods: Electronic databases, conference proceedings, text books and clinical guidelines were searched for quantitative, observational, and prospective clinical intervention studies of female chronic pelvic pain where physiotherapy was a sole or significant component of the intervention. Trial inclusion, data extraction according to predefined criteria and risk of bias assessment were performed by two independent authors. Methodological quality of the included clinical intervention studies was assessed using The Cochrane Collaboration's tool for assessing risk of bias. Review Manager (RevMan) version 5.0 was used for data analysis. Effect estimates (relative risk, mean difference and mean change) with 95% confidence intervals were calculated for the above outcomes. For significant outcomes the numbers needed to treat were calculated.
Results: The search strategy identified 3469 potential articles. Of these, 11 articles, representing 10 studies, met the inclusion criteria. There were 6 randomised clinical trials, 1 cohort study and 3 case series. Methodological quality was dependent on study type. Accordingly, level of evidence was judged higher in randomised clinical trials than in the other study types. Physiotherapy treatments varied between studies and were provided in combination with psychotherapeutic modalities and medical management. This did not allow for the 'stand-alone' value of physiotherapy to be determined. Heterogeneity across the studies, with respect to participants, interventions, outcome measures and times of follow-up, prevented meta-analysis. Narrative synthesis of the results, based on effect estimates and clinically relevant pain improvement, disclosed some evidence to support an effect of multidisciplinary intervention and Mensendieck somatocognitive therapy on female chronic pelvic pain.
Conclusion: Chronic pelvic pain in women is a major health care problem with no specific therapies and poor prognosis. There seems to be some evidence to support the use of a multidisciplinary intervention in the management of female chronic pelvic pain. Somatocognitive therapy is a new approach that appears to be promising and randomised clinical trials are underway in order to establish its evidence base.
Implications: Based on the findings of this review, recommendations for physiotherapy in chronic pelvic pain clinical guidelines, textbooks and narrative reviews should be interpreted with caution due to the lack of a sufficient evidence base. Only small and largely non-randomised studies have been undertaken of physiotherapeutic interventions and this greatly limits the available evidence on which to base clinical practice. High quality randomised clinical trials are therefore urgently needed.

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Contents

1. Introduction

Chronic pelvic pain (CPP) is a debilitating condition among women with a major impact on health-related quality of life, work productivity and health care utilisation. The exact prevalence of chronic pelvic pain is not known, but 3.8% is commonly suggested [1]. A WHO review on the worldwide prevalence of female CPP reports prevalence rates ranging from 2.1% to 24% [2], with a higher prevalence among fertile women [3]. The International Association for the Study of Pain (IASP) defines CPP as chronic or recurrent pelvic pain that apparently has a gynaecological origin but for which no definitive lesion or cause is found [4]. The definition is problematic from a clinical perspective, since it implies the absence of pathology, which may not necessarily be the case [5]. The European Association of Urology (EAU) refines the description of CPP to "non-malignant pain perceived in structures related to the pelvis, constant or recurring over a period of at least 6 months. In some cases it can be associated with negative cognitive, behavioural and social consequences" [6]. This definition allows for a possible overlap of mechanisms between different conditions and hereby a more multimodal treatment approach.

A newly updated Cochrane Systematic Review [7] identifies some evidence for the use of non-surgical interventions in the management of CPP. For example, the use of hormonal drugs was associated with a reduction of pain. Likewise, counselling supported by ultrasound scanning was associated with reduced pain and improvement in mood. A multidisciplinary approach was beneficial for improved function and self-rating of general pain experience. The stated objective of a newly published Cochrane protocol [8] is to assess the effectiveness and safety of non-surgical interventions for women with CPP. Alternatives to surgical management of CPP include analgesics, hormonal drugs, antidepressants, venoconstrictor drugs, psychotherapy focusing on mood and psychological well-being, photographic reinforcement after surgery, magnetic field treatment and writing therapy [9]. Novel approaches like Mensendieck somatocognitive therapy [10] and botulinum toxin to relieve pelvic muscle spasm have also been tried on a small number of women [11]. Many have also used Traditional Chinese Medicine (TCM) in the management of chronic pain. Such treatments include herbal therapy, acupuncture and variations of acupuncture [12].

Physiotherapy is advocated in CPP clinical guidelines [6,13,14], textbooks on (pelvic) pain [15–18], and narrative CPP reviews [11,19–23]. Despite this advocacy, the evidence for an effect of physiotherapy as a sole or significant component in the treatment of CPP is restricted, as no evaluation of effect using systematic methodologies has been conducted. There is evidence that up to 85% of women with CPP have dysfunction of the musculoskeletal system including postural changes as well as changes of the pelvic muscles such as spasm of the levator ani [19,24]. The results of this systematic review could update recommendations regarding physiotherapy treatments for female CPP in clinical guidelines.

1.1. Objectives

To examine current evidence for an effect of physiotherapy as a sole intervention or significant component of a multidisciplinary intervention on pain, physical activity and quality of life in adult women with chronic pelvic pain.

Table 1
Keywords used to develop the search strategy.

Population/problem		Intervention	
Pelvic pain/pain-pelvic (syndrome)	Cystitis, interstitial/interstitial cystitis (IC)	Physical therapy/physiotherapy	Massage
Chronic pelvic pain (CPP)	Bladder pain syndrome/painful bladder syndrome (BPS/PBS)	Physical treatment	Mobilisation (therapy)
Pain-abdominal/abdominal pain	Urethral pain syndrome	Physical exercise therapy	Musculoskeletal manipulation
Pelvic tenderness		Ultrasonic (therapy)	
Pelvic pressure	Irritable bowel (syndrome) (IBS)	Ultrasound (therapy)	Multidisciplinary
Pelvic venous congestion	Colonic disease, functional	Stretching	Interdisciplinary
Pelvic congestion (syndrome)	Irritable colon	Electro (therapy)	Multiprofessional
Pelvic adhesion	Functional bowel disease	Electromyographic (therapy)	Multimodal
	Spastic colon	Transcutan nervestimulation (TENS)	Patient care team/management
		Manual therapy	Pain clinics/-centre/-service/-relief units
			Rehabilitation centres/-clinic

2. Method

2.1. Information sources

The search strategy and index terms were planned by the first author (SL) under guidance of a clinical expert (JN) and the supervisor group (PJ, TT). The search strategy was inspired by the search words developed by the Cochrane specialised register group; i.e. the Menstrual Disorders and Subfertility Group, The Incontinence Group, The Functional Disorder Group and The Musculoskeletal Group.

The primary search was conducted in April 2010, and updated in September 2010, April 2011, and latest in September 2011. This revealed no new relevant studies. The electronic databases Medline (1966–2011), Embase (1980–2011), Cinahl (1982–2011), PsycINFO (1995–2011), and the following evidence-based practice resources; CENTRAL (1987–2011), Physiotherapy Evidence Database (PEDro, Centre for Evidence Based Physiotherapy 2010/2011), and Database of Abstracts of Reviews of Effects (DARE 2011) were searched. The search contained keywords (Mesh and Thesaurus) and was a combination of searches in Keywords and Title/Abstract to ensure that all new studies were included. Multiple keywords to describe CPP and physiotherapy modalities were used reflecting the lack of a consensus definition and of validated diagnostic markers in categorizing CPP [6] and the range of physiotherapy interventions and the terminology to describe such interventions (Table 1).

2.1.1. Searching other resources

- The reference lists of all papers meeting the inclusion criteria, other relevant publications and review articles.
- Hand search of relevant journals, abstracts, conference proceedings and key grey literature sources.
- We personally contacted the authors for further information, if needed.

2.2. Study selection

Titles were scanned by the first author (SL) and obviously irrelevant studies were removed. Abstracts of potentially eligible studies were reviewed by two authors (SL and TT). The first author (SL) is knowledgeable in the area under review, the second author (TT) is not a content expert but has experience with conducting systematic reviews. Disagreements concerning the relevance of the studies for the review were resolved by discussion. A third assessor was available as an arbiter in case of disagreement. Papers were included in this systematic review if they met the inclusion criteria listed in Table 2. The full text versions of all papers that met the inclusion criteria were retrieved for data extraction and risk of bias assessment.

2.3. Critical assessment of included studies

Critical appraisal of each included study was conducted by determining:

Table 2
Eligibility criteria used in the systematic review.

	Criterion	Justification
1	Females over 19 years of age with CPP	This increases the homogeneity of participants between the studies
2	Diagnostic criteria for CPP	Including: pelvic adhesion, pelvic congestion syndrome, bladder pain syndrome, urethral pain syndrome and irritable bowel syndrome. Excluding: malignancy, primary dysmenorrhoea, endometriosis, pregnancy, infections, active chronic pelvic inflammatory disease and vulvodynia/vulvar pain syndrome
3	Experimental intervention of physiotherapeutic intervention alone or in combination with other medical or psychological therapies	As multidisciplinary management of CPP is considered optimal [7], studies that involve physiotherapy in combination with other interventions were included. Control interventions could include treatment as usual, no treatment, surgery, medical treatments or placebo treatments
4	Types of outcome measurements	Pain measured with validated pain scores/-scales or descriptive endpoints, quality of life assessed by validated questionnaires, and physical activity assessed with validated measurement instrument
5	Prospective quantitative study design including randomised clinical trials (RCTs), non-randomised clinical trials (NRCTs), cohort studies or case-series	Based on a former systematic review of intervention on chronic pelvic pain [7], inclusion of only *randomised clinical studies* was not feasible. Retrospective studies or studies with historical controls were excluded. Randomised clinical trials had preferential priority

Diagnostic criteria: when data included only a subgroup of patients who met our inclusion criteria, these subgroups were included in the analyses.
Experimental intervention: included, exclusively or partially, any physiotherapeutic intervention for the management of CPP. Physiotherapeutic interventions could include the following: exercise therapy, manual therapy, stretching, ultrasound, musculoskeletal therapy, electromyographic therapy/biofeedback, transcutane nerve stimulation.

- The level of evidence for an intervention effect in the included studies using The Cochrane Collaboration's tool for assessing risk of bias. The tool is recommended for experimental and controlled studies and involves consideration of six features: sequence generation, allocation sequence concealment, blinding, incomplete outcome data, selective outcome reporting and "other" potential sources of bias. Items in the risk of bias assessment were judged "adequate" (+), "unclear" (?), or having the "potential for bias" (−) for each study (Fig. 2). Blinding of participants in a physiotherapeutic intervention is nearly impossible, and complete blinding of personnel/therapists was considered difficult to uphold. We therefore judged blinding as adequate if outcome assessors were blinded.

  The Cochrane Collaboration's tool for assessing risk of bias was not developed for non-randomised clinical studies (NRCTs). The six domains included in the tool could usefully be assessed for prospective cohort studies as recommended by the Cochrane Collaboration, but are not necessarily sufficient for assessing risk of bias. As recommended by the Non-Randomised Studies Methods Group (NRSMG) of the Cochrane Collaboration we chose to additionally assess the potential risk of confounding in the included studies that were not RCTs under guidance by NRSMG. We prespecified the following potential confounding factors; age, duration of pain, number of pain sites, depression, sexual dysfunction, earlier pelvic operation for the pain, and history of sexual or physical abuse.

- A categorization of systematic error (bias) of the included clinical intervention studies into levels of evidence proposed by The Cochrane Hepato-Biliary Group, Copenhagen Trial Unit, Rigshospitalet, Denmark. Trials with one or more bias components assessed as inadequate or unclear were considered to be at high risk of bias, while trials with all quality components assessed as adequate were considered to be at low risk of bias [25].

2.4. Data extraction and management

A standard review checklist based on guidelines in the Cochrane Handbook [26] was used independently by the review authors to extract data for each included trial. Information was collected in PICO(S) structure: patients, intervention, control, outcome measure (and time of follow-up) and study design [25]. The following data were reported in "Characteristics of the included studies" (Table 3).

- Study design and country site.
- Type of chronic pelvic pain (unspecified, related to the reproductive system, the bladder or the bowel) and duration.
- Number and characteristics of study participants.
- Description of experimental interventions, including extent and duration; description of control intervention if any.
- Outcomes and time points collected and reported.
- Drop-out rate.

Data were initially extracted from each trial by SL and subsequently verified for consistency and accuracy by TT. We resolved disagreement by discussion until consensus was reached.

Risk of bias assessment of the included studies is summarised in Fig. 2 and Categorization of bias into levels of evidence is described in Table 4.

We used Review Manager (RevMan) version 5.0 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) for data analysis. Data on the primary outcome (pain) are presented in Tables 5a–c; data on secondary outcomes (physical activity, quality of life) are narratively summarised. Most of the included RCTs compared outcome improvement as within-group pre- and post-treatment results instead of calculating between group differences. We judged between-group analyses to be more informative based on the randomised clinical study design. We calculated mean differences (MD) and 95% confidence intervals (CI) for continuous measurements from comparative studies (Table 5a). For binary (or dichotomous) outcomes, we calculated risk ratios (RRs), the corresponding 95% CIs using Mantel–Haenszels methods (Table 5b), and for significant results the numbers needed to treat (NNT). For non-comparative studies we expressed results for each study as mean changes between pre- and post-treatment with 95% CIs and *p*-values 3 (Table 5c).

2.5. Types of outcome measures

Core outcomes were based on the recommendations of Cochrane Pain, Palliative and Supportive Care Review Group (PaPaS). We considered measures on pain reduction, quality of life and physical functioning/activity to be important outcomes in this systematic review.

The primary outcome was pain reduction measured on validated pain scores, scales or questionnaires or by descriptive endpoints. Considerable effort has been devoted into quantifying the magnitude of change in pain intensity that is considered clinically relevant to patients with chronic pain [27–29]. A moderately important benefit is defined as at least 30% reduction in pain and a substantial important benefit as at least 50% reduction [30]. Clinical studies reporting average changes in pain scores are of limited utility and often inappropriate. The average results represent only a small minority of patients as responses in chronic pain trials frequently take the form of a skewed or bi-modal distribution, where some patients obtain very good pain relief while others obtain very little [31–33]. Therefore, when sufficient raw data (individual patient data) were provided in the articles [10,34] we dichotomised improvement in pain scores according to the above clinically relevant criteria.

Secondary outcomes were measures of quality of life (QoL) and physical functioning/activity measured by validated questionnaires or rating scales. We summarised analyses on statistically significant results.

We reported other relevant outcomes such as depression, general pain, associated symptoms, medicine intake and pelvic floor muscle strength as in the original studies in Table 3 (Characteristics of the included studies). Due to substantial heterogeneity in outcome reporting between studies, these outcomes were not pooled.

We considered analyses of reports of sexuality and patient global impression of intervention important for women with CPP and therefore summarised these outcomes as reported by included studies.

Adverse events: We summarised adverse events as reported by included studies.

2.6. Duration of intervention effect and follow-up period

Intervention effects decrease over a period of 2–12 weeks, especially of minimally effective interventions [31]. We therefore considered 10–12 weeks duration of intervention and follow-up as a minimum requirement, not least in light of the chronicity of the condition and the likelihood of a 12-week measurement becoming standard [31].

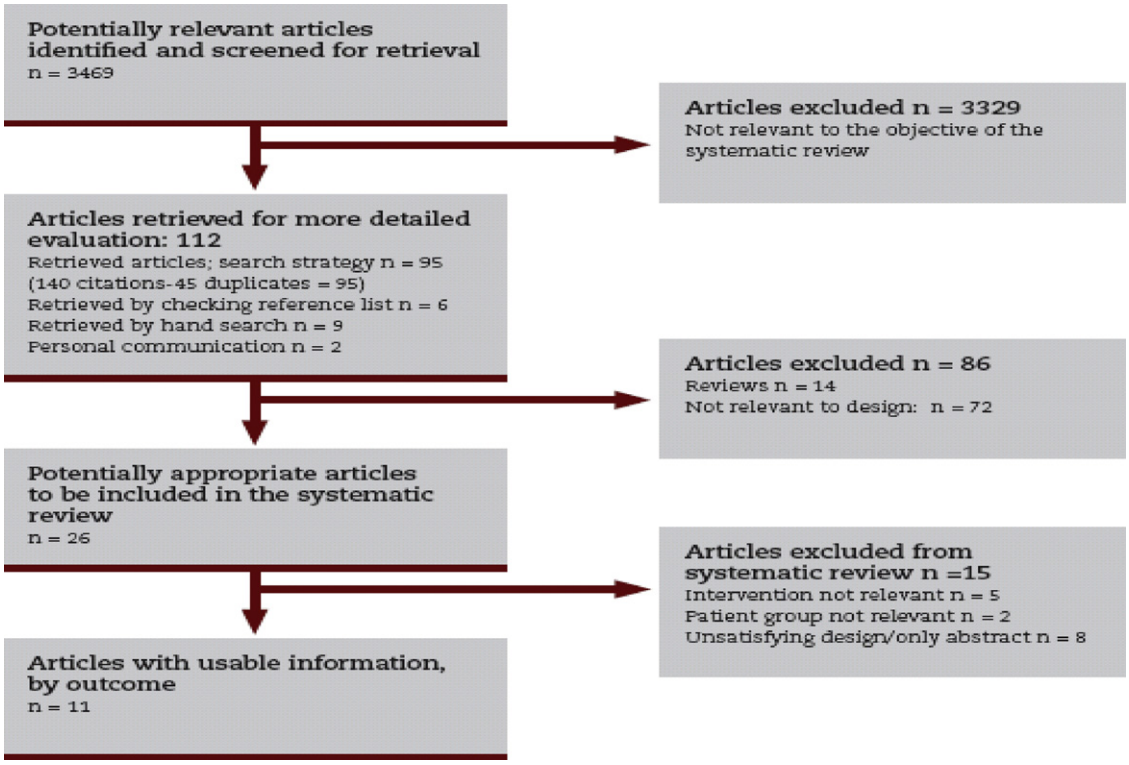

Fig. 1. Retrieval and review process.

3. Results

3.1. Search strategy yield

The search strategy identified 172 citations in MEDLINE, 73 in Cinahl, 1656 in EMBASE, 1542 in Cochrane and 26 in Pedro, yielding 3469 unique citations. Ninety-five out of 140 potentially eligible citations were identified after reviewing the titles of the 3469 citations and after removing duplicates (45 citations). Six additional, potentially eligible studies were found from reference lists in the studies retrieved through the search, nine studies were retrieved by hand search, and two studies were obtained through personal communication. The resulting 112 records were screened and 86 records were excluded on the basis of information provided in the abstracts. Of the 26 remaining, potentially eligible studies, 15 were excluded in accordance with the inclusion criteria (Fig. 1). Eleven clinical trials involving initial recruitment of 782 participants were included (Table 3). One study had different outcomes reported in additional papers; Haugstad reported 1-year follow-up in 2008. We reported outcomes using the main study identifier [10].

Seven authors were contacted [35–41] for information on publication of abstracts, gender- or diagnosis-specific data (raw data), or study design. This lead to preliminary inclusion of two conference proceedings [39], one abstract [38] and one article [37] retrieved through the electronic search strategy. The remaining authors either did not respond or could not give the requested information.

3.2. Characteristics of included studies (Table 3)

3.2.1. Study design and publication

Six studies were RCTs [10,37,42–45], one was a cohort study [46] and three were case-series [47–49]. Three studies originated from Scandinavia, one from The Netherlands, two from Brazil and the remaining four trials from the USA. The studies were published from 1991 to 2010.

3.2.2. Participants

Sample sizes ranged from 21 to 370 participants, with a mean of 78. Subjects were recruited from university hospitals and specialist clinics. In all but two RCTs [43,45] sample sizes were based on a pre-trial power analysis, whereas none of the NRCTs reported power calculations. All studies listed or referenced their diagnostic criteria for CPP. The IASP criteria [4] or the refined diagnostic criteria by EAU [6] were most frequently used. Apart from one study [37] all participants were women. Following discussion and correspondence with the study authors, this RCT was included in the systematic review as the predominantly female population (92%) in the PBS/IC subgroup was judged relevant to this review.

Participant characteristics varied across the studies. Mean ages ranged from 30.5 to 43 years, and mean durations of pain from 2.8 years [44] to 6.33 years [10]; five studies did not provide this information [37,42,43,47,48]. Six studies specified a minimum six-months duration of CPP symptoms as an inclusion criterion, one RCT specified three months [45], one RCT between 1-10 years [10], another RCT less than 3 years [37] and one NRCT did not define inclusion criteria for duration of symptoms [48]. Pre-specified potential confounders in the NRCTs included no consensus in reporting of number of pain sites, depression, dyspareunia, previous pelvic surgery, physical or sexual abuse, sexual dysfunction or social factors.

3.2.3. Types of intervention

Physiotherapeutic interventions, treatment frequencies and duration varied substantially across studies. Interventions included psychosomatic group treatment, intravaginal electrical stimulation, myofascial physical therapy, stretching, Mensendieck somatocognitive therapy, manual trigger point therapy, multidisciplinary treatment (pharmacotherapy, psychotherapy, physiotherapy) or Thiele massage. In all but one study physiotherapy was a major [10,37,44–46,49] or sole [42,47,48] component of the interventions provided. The RCT by Hawk examined a

Table 3
Characteristics of the included studies.

Author	Study design	Participants		Intervention		Outcome		Drop-out at latest follow-up [%]
		n	Sample characteristics	Experimental	Control	Outcome instruments (relevant)	Time of outcome assessment	
Albert (1999) Denmark	Case-series	53	CPP > 6 months, mean duration 5.9 years All females, mean age 30.5 No gynaecological diseases, no cancer, no psychological disorders	Group treatment • Physical • Psychosomatic • Behavioural Duration: 10 weekly treatments	None	Pain (VAS) Medicine intake Time spent sitting, standing and lying	1 year	26%
Bernardes (2005) Brazil	Case series	24	CPP ≥ 6 months, mean duration NR All females, mean age 35.8 All urogynaecological examinations normal	IVES: intravaginal electrical stimulation Duration: 10 sessions, 2-3 times a week	None	Pain (VAS)	• End of treatment • 2 weeks post test • 4 weeks post test • 7 months	0%
Bernardes (2010) Brazil	RCT, double blind, cross-over design	26	CPP ≥ 6 months VAS > 3 Mean duration NR All females, mean age 40 All urogynaecological examinations normal	10 sessions active IVES Duration: 10 weeks	10 sessions of placebo IVES Cross-over design: subjects acted as own controls	Pain (VAS) in categories: • None (0) • Low (1–3) • Moderate (4-7) • Intense (8–10)	End of treatment (10 weeks)	4%
FitzGerald (2009) USA	RCT, multicenter	47 (total) 26 (analyses)	IC/PBS or CP/CPPS, symptoms < 3 years, mean duration NR IC/PBS group 24 females, 2 men, mean age 43	Myofacsial physical therapy (MPT) Duration: 10 weekly treatments of 1 h	Global therapeutic massage (GTM), 10 weekly treatments of 1 h duration.	• Pain (VAS) • SF-12 physical • SF-12 mental	End of treatment (12 weeks)	6%
Haugstad (2006) Norway	RCT	40	CPP between 1 and 10 years, mean duration 6.33 years All females, mean age 33.3	Standard gynaecological treatment (STGT) and Mensendieck somatocognitive therapy (MSCT) Duration: 3 months (90 days)	Standard gynaecological treatment (STGT) at inclusion and 1 more time during the treatment period	Pain (VAS) Motor function GHQ-30	End of treatment (90 days) 1 year follow-up	5% 7.5%
Hawk (2002) USA	RCT	39	CPP ≥ 6 months, mean duration NR All females, mean age 34.2	Chiropractic techniques and manual trigger point therapy Duration: 6 weeks, 2–3 times per week	Sham adjusted chiropractic combined with effleurage (light massage)	• Pain (PDI) • Pain (VAS) • Pain (MPQ) SF-36	End of treatment (6 weeks)	8%

Table 3 (*Continued*)

Author	Study design	Participants		Intervention		Outcome		Drop-out at latest follow-up [%]
		n	Sample characteristics	Experimental	Control	Outcome instruments (relevant)	Time of outcome assessment	
Heyman (2006) Norway	RCT	50	CPP ≥ 6 months min. 2 days a week, mean duration 2.8 years All females, mean age 33.5	Distension of the pelvic floor (2 sessions) and counselling Duration: 2–4 weeks	Treatment as usual, counselling (1 session)	• Pain (VAS) • Quality of life (VAS)	2–3 weeks after end of treatment	12%
Lamvu (2006) USA	Prospective cohort study	370	CPP ≥ 6 months, mean duration 4.6 years All females, mean age 33 15 different clinical pelvic diagnoses included	Medical intervention/surgery: • Pharmacotherapy • Psychotherapy • Physiotherapy Surgery • Duration: frequency & duration NR	None	Pain (MPQ) Change in pain • Worsened • No change • Improved • Resolved	1 year	– 62% non-responders
Oyama (2004) USA	Case series	21	IC and high tone pelvic floor dysfunction, duration of IC range 5–14 years All females, mean age 42	Modified Thiele massage Duration: twice a week for 5 weeks		Pain (VAS) SF-12 (physical) SF-12 (mental) Modified Oxford Scale	Baseline 2 weeks post-test 4.5 month follow-up	0% 38%
Peters (1991) The Netherlands	RCT	112	CPP ≥ 3 months, mean duration 3.5 years All females, mean age 35.6	Multidisciplinary approach incl. surgery, drug treatment, dietary-, physiotherapy- and psychosocial intervention Duration: 6 months	Standard diagnostic laparascopy	• General pain experience • Disturbance of daily activities • Associated symptoms • Pain (McGill score)	One year	5%

NR: not reported, GHQ-30: psychological distress & well-being, VAS: visual analogue scale, PDI: pain disability index, MPQ: McGill pain questionnaire, CP: chronic prostatitis, CPPS: chronic pelvic pain syndrome, IC: interstitial cystitis, PBS: painful bladder syndrome.

chiropractic technique, which we chose to include because it resembled a similar physiotherapeutic intervention, manual trigger point therapy. Treatment duration across studies varied from 2-4 weeks [44] to 6 months [45] with very heterogeneous treatment frequencies, if reported at all.

3.2.4. Use of control groups

Control interventions also varied and included surgery, placebo intervention (sham intravaginal electrical stimulation, sham chiropractic or global therapeutic massage) or standard gynaecological treatment. Standard gynaecological treatment included general information concerning diagnosis, hormonal treatment, analgetics, dietary and/or sexologic advice [10] or standard diagnostic laparoscopy to exclude organic causes [45].

3.2.5. Outcome measures

Outcome measures differed substantially across studies; visual analogue scales (VAS) for pain, McGill pain score (MPQ), O'Leary-Sant IC problem and symptom Index, Female Sexual Function Index (FSFI), Pain Disability Index (PDI) and Beck Depression Inventory (BDI), SF-12 and SF-36, measures of pain medicine intake, measurements of daily activity/motor function, psychological distress & general well-being (GHQ-30), and general pain experience. Pain was the most commonly measured variable, but was quantified differently (dichotomized, categorized or continuous) across studies. Moreover, measurement times and follow-up times varied, ranging from 2-3 weeks to one year.

Outcome measures on Patient Global Response [37], General Health Questionnaire [34], dyspareunia [42,47], FSFI [37], sexual functioning and sexual abuse [44,46] were only sparsely reported and analyses could not be pooled.

3.2.6. Adverse events

Adverse events (AE) were overall sparsely reported in the included studies. Only three studies reported minor AEs with pain being the most frequently reported [37,44,46]. In two of these studies minor adverse events study-withdrawals ($n \leq 2$) were reported [37,44] due to unspecified pain or a mild temporary increase in local pain.

3.2.7. Time of follow-up

Heterogeneous follow-up times ranging from 2-3 weeks to one year were reported. Only four studies had 1- year follow-up and 3 studies had less than 12-weeks follow-up. This should be taken into account when interpreting the results (Table 3).

3.2.8. Drop-out rate

In all RCTs except one [44] follow-up rates were good with 8% or fewer lost to follow-up. For NRCTs a substantial drop-outs were seen, especially at one year follow-up (see Table 3).

3.3. Critical appraisal

3.3.1. Risk of bias (internal validity)

3.3.1.1. Randomised clinical trials. Three RCTs had level 1b evidence with low risk of bias and three RCTs had level 1d evidence with high risk of bias (Table 4).

Sequence generation and allocation concealment was graded adequate in the publications [10,42,43] or following confirmation from the authors that a robust method of randomisation had been employed [37,45]. Following discussion the review authors judged allocation concealment as adequate in the study by Haugstad [10] despite an unsure random component, i.e. drawing of lots with the *patients' name*. Heyman [44] used stratified block randomisation in blocks of four, which may have enabled prediction of allocation (unclear risk of bias).

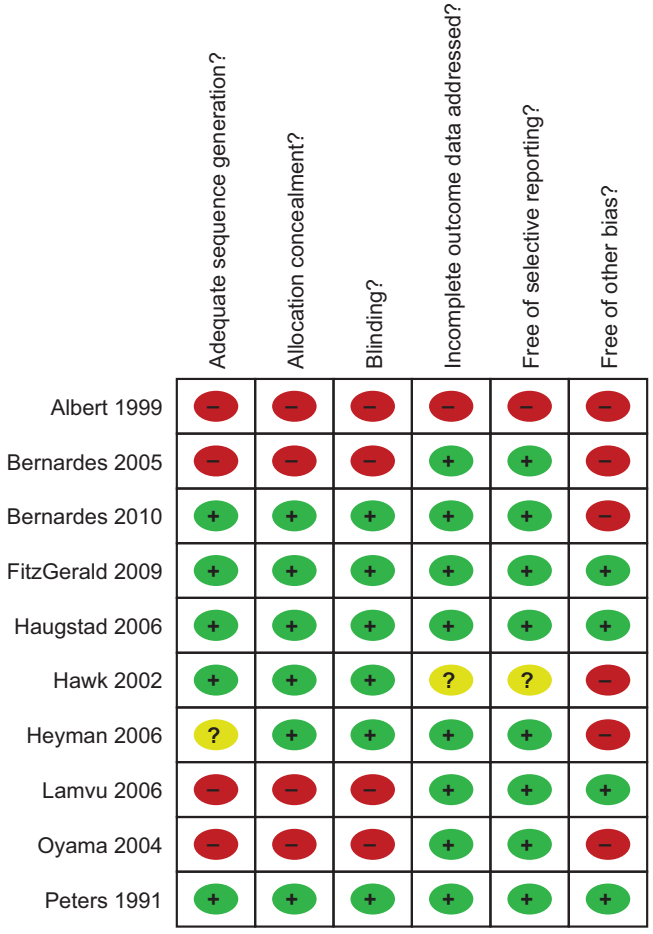

Fig. 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Outcome assessment and blinding were graded adequate in all RCTs except one where no intention-to-treat analysis was conducted [43]. Outcomes as pre-specified in the article were reported in all the six RCTs except for one [10]; Haugstad included a non-prespecified questionnaire assessing psychological distress and general well-being (GHQ-30) at 1 year follow-up [34]. These outcomes are irrelevant to the outcomes analysed in this systematic review. Hawk reported all outcomes at baseline and at the 6-week follow-up, but failed to report outcomes at the 12 and 24 week follow-up as otherwise prespecified in the article. Three of the six randomised clinical trials were reports of feasibility/pilot studies [37,43,44]. One multicentre study reported substantial deviation from study protocols between the participating centres. These deviations prevented pooled analysis of data from all centres [43]. A crossover RCT [42] did not state a wash-out period between treatment periods, which may have introduced a "carry-over" of treatment effect. This led to a judgement of high risk of bias and hereby a lower level of evidence.

3.3.1.2. Non-randomised clinical trials. All NRCTs were judged at high risk of bias except for one [46], which we judged had a moderate quality level.

Due to the NRCT design, generation of allocation sequence and allocation concealment was irrelevant [46–49]. Neither participants, personnel nor assessors were blinded in these studies so we judged outcome measures at potential risk of performance and detection bias. All but one NRCT [47] had substantial drop-out at one-year follow-up. The cohort study had 62% non-responders, however a drop-out analysis revealed no difference between

Table 4
Categorization of systematic error (bias) into levels of evidence.

Category	Studies	Results
Level 1a	Meta-analysis of randomised trials with low risk of bias	
Level 1b	Randomised trial with low risk of bias	FitzGerald (2009), Haugstad (2006), Peters (1991)
Level 1c	Meta-analysis of all randomised trials	
Level 1d	Randomised trials with high risk of bias	Bernardes (2010), Hawk (2002), Heyman (2006)
Level 2a	Meta-analysis of cohort studies	
Level 2b	Cohort study	Lamvu (2006)
Level 3a	Meta-analysis of case–control studies	
Level 3b	Case–control study	
Level 4	Case-series	Bernardes (2005), Albert (1999), Oyama (2004)
Level 5	Expert opinion	

responders and non-responders in baseline characteristics [46]. Three NRCTs reported all outcomes as prespecified [46–48]. Albert [49] omitted reports of time spent sitting, standing or lying and state of mood, and neither outcome measurements on pain were reported at end of treatment and at 3 months follow-up as otherwise prespecified. Instead, only outcomes at 1 year follow-up were reported.

3.3.1.3. Summary. Fig. 2 illustrates a general high risk of bias across the included studies (one or more component rated as inadequate or unclear). Three randomised trials were rated as level 1b evidence with low risk of bias, three RCTs as level 1d evidence with high risk of bias. The cohort study was rated level 2b evidence and the remaining three non-randomised trials level 4 evidence (Table 4). Studies high on the hierarchy potentially contain less bias than those lower on the hierarchy.

3.4. Effect of physiotherapy as a sole or significant component of a multidisciplinary intervention

3.4.1. Results of individual studies (Tables 5a–c)

3.4.1.1. Randomised clinical trials and comparative studies (Tables 5a and b). In women undergoing Mensendieck somatocognitive therapy [10,34] significant improvements in pain were identified at the end of treatment (90 days), and the effect lasted with continued improvement occurring up to 9 months after treatment [34]. This result seems clinically relevant with average pain scores improving more than 50% [95% CIs ranging from 33 to 87%] (Table 5a). Haugstad [10,34] provided raw data on pain improvement from baseline to 90 days and to 1-year follow-up. We dichotomised these data according to a minimum pain improvement of 30% and 50%, respectively (Table 5b). Both criteria were satisfied at end of treatment (3 months) and at 1-year follow-up. For 50% pain improvement at 90 days the number needed to treat between groups was 2; for 50% pain improvement at 1-year follow-up NNT was 3 (Table 5b).

Multidisciplinary interventions compared to standard diagnostic laparoscopy led to improved outcomes at 1-year follow-up, both in general pain experience measured on a self-rating scale and in daily activities [RR 1.86; CI 1.24–2.80]. The number needed to treat was 3. No improvement was identified in McGill pain scores [45]. Likewise, the cohort study identified no improvement in McGill pain scores between surgical and multidisciplinary treatment at 1-year follow-up [46].

Significant average improvements in pain scores [62%; CI 43–83%] were seen 2–3 weeks after treatment in women receiving distension of the pelvic floor muscles [44]. Interpretation of the potential clinical relevance of this average improvement is difficult. Furthermore the short follow-up precludes evaluation of any long-term effect of the intervention.

10 weeks of intravaginal electrical stimulation compared to placebo IVES did not demonstrate a between-group significant reduction ($p = .07$) in pain [42]. Likewise, no between-group statistical significant reduction ($p = .07$) in pain scores was seen after 12 weeks of myofascial physical therapy in women with IC/PBS compared to global physical massage [37].

Measures on physical function showed significant improvements in movement [MD 1.24; CI 0.54–1.94] and in gait [MD 1.15; CI 0.37–1.93] at 1 year follow-up following somatocognitive therapy. For respiration and for sitting-posture as well significant improvements were seen both at the end of treatment and at 1 year follow-up measured by the validated Mensendieck motor function test [10,34]. Where quality of life outcomes were included in the original study these did not improve significantly [37] or were not reported because of missing data [43,44]. Effect estimates could not be calculated for one RCT due to missing data [43].

Two studies demonstrated significant pre-post pain reduction in control-groups [45,46], whereas pre-post pain improvements (if reported) were non-significant in the remaining studies.

Table 5a
Effect of physiotherapy intervention on continuous pain outcomes (RCTs).

Ref.	Physiotherapy intervention	Pain measures	Time of follow-up	I Mean ± SD	C Mean ± SD	MD between groups in pain measures [CI 95%]	Pain reduction in percent [CI 95%]
FitzGerald (2009)	MPT	VAS	End of treatment (12 weeks)	4.2 SD 2.9	5.9 SD 2.0	−1.70 [−3.75, 0.35]	NS
Haugstad (2006)	MSCT	VAS	End of treatment (3 month) 1 year follow-up	2.89 SD 1.79 2.00 SD 1.65	6.16 SD 2.24 5.95 SD 2.73	−3.27 [−4.53, −2.01][a] −3.95 [−5.35, −2.55][a]	53% [33–74] 64% [42–87]
Hawk (2002)	Chiropractic	VAS PDI MPQ	End of treatment (6 weeks)	Effect estimate calculation not possible due to incomplete data addressing			
Heyman (2006)	Distension of PFM	VAS	2–3 weeks after treatment	2.9 SD 2.8	7.1 SD 1.8	−4.20 [−5.59, −2.89][a]	62% [43–83]

MPT: myofascial physical therapy, MSCT: Mensendieck somato-cognitive therapy, PFM: pelvic floor muscle, VAS: Visual analogue scale, PDI: pain disability index, MPQ: McGill pain questionnaire, I: intervention group, C: control group, SD: standard deviation, MD (mean difference): a negative mean difference favours a physiotherapy treatment effect, i.e. decrease in pain level (VAS), CI: confidence interval, here defined as 95% CI.
NS: non-significant.
[a] Statistically significant.

Table 5b
Effect of physiotherapy intervention on dichotomised pain outcomes (RCTs or comparative cohort studies).

Ref.	Physiotherapy intervention	Pain measures	Time of follow-up	I	C	RR between groups for pain improvement [95% CI]	NNT for significant results
				N (total) (%)	N (total) (%)		
Bernardes (2010)	IVES	VAS, categorized into 4 groups[b]	End of treatment (10 weeks)	13 (15) (87%)	6 (11) (55%)	1.59 [0.89, 2.82]	
Haugstad (2006/2008)	MSCT	VAS, dichotomised >30% pain reduction	End of treatment(3 month)	14 (19) (74%)	3 (19) (16%)	4.67 [1.60, 13.64][a]	2
			1-year follow-up	16 (18) (89%)	6 (19) (32%)	2.81 [1.42, 5.57][a]	2
Haugstad (2006/2008)	MSCT	VAS, dichotomised >50% pain reduction	End of treatment (3 month)	13 (19) (68%)	3 (19) (16%)	4.33 [1.47, 12.79][a]	2
			1-year follow-up	11 (18) (61%)	5 (19) (26%)	2.32 [1.00, 5.37][a]	3
Lamvu (2006)	Multidisciplinary incl. physiotherapy	Change in pain level MPQ[c]	1-year follow-up	82 (181) (45%) 115 (181) (64%)	87 (189) (46%) 131(189) (69%)	0.98 [0.79,1.23] 0.92 [0.79,1.06]	
Peters (1991)	Multidisciplinary incl. physiotherapy	MPQ[c]	1-year follow-up	35 (57) (61%)	25 (49) (51%)	1.20 [0.85, 1.70]	
		General pain experience		43 (57) (75%)	20 (49) (41%)	1.85 [1.28, 2.67][a]	3

IVES: intravaginal electrical stimulation, Multidisciplinary: pharmacotherapy, psychotherapy, physiotherapy, VAS. Visual analogue scale, PDI: pain disability index, MPQ: McGill pain questionnaire, I: intervention group, C: control group, N: number, SD: standard deviation, CI: confidence interval, NNT: number needed to treat, RR: a positive risk ratio favours a physiotherapy treatment effect, i.e. decrease in pain level (VAS) by group assignment.

[a] Statistically significant.

[b] Dichotomised into 2 groups. None or low pain (VAS ≤ 3) vs. moderate or intense pain (VAS 4-10).

[c] MPQ score: decrease of 1 point or more from baseline.

Table 5c
Effect of physiotherapy intervention on pain, produced from non-randomised and non-comparative clinical trials.

Ref.	Physiotherapy intervention	Time of follow-up	Pre-intervention pain Mean (SD)	Post- intervention pain Mean (SD)	Mean change; pre- and post-intervention pain measures [95% CI][a]	*p*-value
Albert (1999)	Group treatment incl. physiotherapy	1-year FU	2.9 (2.0)	0.9 (1.5)	−2.0 [−1.43, −2.57]	<.01
Bernardes (2005)	IVES	End	8.3 (1.76)	1.0 (1.96)	−7.3 [−6.51, −8.09]	<.05
		2 weeks AT		2.8 (3.38)	−5.5 [−4.41, −6.59]	<.05
		4 weeks AT		3.2 (3.77)	−5.1 [−3.93, −6.27]	<.05
		7 month AT		2.1 (3.48)	−6.2 [−5.09, −7.31]	<.05
Oyama (2004)	Modified Thiele Massage	2 weeks AT	5.4	3.5	−1.9 [CI not possible]	=.001
		4½ month AT		2.6	−2.8 [CI not possible]	=.005

Group treatment: physical, psychosomatic and behavioural therapy, IVES: intravaginal electrical stimulation, FU: follow-up, AT: after treatment, Negative mean changes favour a physiotherapy treatment effect, i.e. decrease in pain level (VAS).

[a] 95% CI = difference $\pm T \times SD/\sqrt{n}$.

Information on other outcomes was inconsistently reported and could not be summarised.

3.4.1.2. Non-randomised and non-comparative studies (Table 5c). The results of the NRCTs and non-comparative studies are presented in Table 5c. Significant changes for three different kinds of physiotherapeutic modalities are illustrated. 95% CIs could not be calculated for one NRCT because of missing data [48]. Instead *p*-values presented by the study authors are included.

Group treatment based on physical, psychosomatic and behavioural therapeutic principles of treatment reduced pain intensity significantly at 1-year follow-up [49]. Intravaginal electrical stimulation was effective when utilised for the relief of pain in women with CPP up to seven months after treatment [47]. Modified Thiele massage of the pelvic floor muscles in women with PBS/IC and high tone pelvic floor dysfunction provided significant reduction in pain (VAS) both at 2 weeks and 4 months after treatment [48].

3.5. Synthesis of results

Neither data gained from RCTs nor NRTCs could be pooled because of heterogeneity of participants, interventions, outcome measures, and follow-up times. This prevented synthesis of results across studies and hereby also meta-analyses.

4. Discussion

4.1. Summary of evidence

The results of this systematic review indicate that there is level 1b evidence (low risk of bias) that Mensendieck somatocognitive therapy combined with standard gynaecological care improves pain experience in female CPP [10,34]. The results are clinically relevant with point estimate reductions in pain exceeding 50%. This effect persisted nine months post-treatment. A growing body of evidence is establishing that a 50% reduction in pain experience or more is associated with major improvements in function, sleep, fatigue, depression, quality of life and ability to work [50–53]. This supports the significant results on physical function, gait, respiration and sitting posture following somatocognitive intervention [10,34].

There is level 1b evidence (low risk of bias) for an effect of a multidisciplinary intervention including physiotherapy compared to standard diagnostic laparoscopy on the general experience of

pain and level of daily activity in women with CPP. However, the minimum level of pain improvement required to demonstrate a statistically significant effect was not specified in the article, and the clinical relevance is therefore uncertain. Notably, no improvement was demonstrated in specific pain measurements (McGill) [45], a finding that is similar to the findings of the comparable intervention study by Lamvu 2006 [46]. Both studies had sufficient follow-up periods (1 year) whereas duration of treatment was only specified in one (6 months).

There is level 1d evidence (high risk of bias) that physiotherapeutic distension of painful pelvic structures combined with pain counselling improves pain experience compared to TAU (1 counselling session). The clinical relevance of this result is however difficult to assess because the experience of pain is evaluated as a group average and because of the short follow-up period.

Insufficient level of evidence is provided to draw conclusions in regard to the effect of psychosomatic group treatment [49], and to Modified Thiele Massage [48], even though studies of these interventions demonstrated a statistically significant pre-post reduction in pain on VAS.

It was not considered possible to meta-analyse the results of the included studies, which is a limitation of this review. Moreover, the majority of the studies included, investigated the effect of physiotherapy in combination with medical or psychological treatment. Therefore the stand-alone value of a physiotherapeutic treatment modality cannot be determined. By reference to the risk of bias assessment of the individual studies (Fig. 2), the categorization into levels of evidence (Table 4) and the clinical relevance of pain improvement, careful consideration must be kept in mind in the analyses of results and the conclusions drawn from the studies.

4.2. Internal validity

Internal validity was assessed in the risk of bias assessment of the included studies. Internal validity was generally limited by small and potentially selected samples, heterogeneous or unspecified patient characteristics (confounding factors, especially in NRCTs), questionable allocation concealment, lack of blinding, inadequate outcome data addressed and selective reporting.

Small sample sizes and substantial variation in measurements of effects (SD) and wide confidence intervals introduce a risk of random error, especially the type II error (β). The consequence is a risk of false acceptance of "no-effect of intervention". This has to be kept in mind in the interpretation of studies with small sample sizes in which statistical significance (α) is only nearly reached, resulting in rejection of an "intervention effect" [37,42].

4.3. External validity

An overall problem was the lack of flow-charts stating how many women were initially assessed for eligibility and how many of these accepted to participate: FitzGerald (2009) had an unsatisfying presentation of consenting participants (38%), Hawk reported that 92% of eligible women accepted participation, but could not subsequently provide any useful results. The remaining eight papers presented no flow-chart preventing assessment of the potential for an overall risk of selection bias. This poses a potential risk to the external validity of this systematic review and hereby its applicability to clinical practice [54].

Inadequate duration of pain treatment and heterogeneous follow-up times in the included studies also constitute a potential limitation of this review. Chronic pain conditions require treatment for considerable periods of time. In this systematic review only four studies [34,45,46,49] reported follow-up up to 1-year post-treatment, and of these only two RCTs were at low risk of bias. This may affect the external validity of the evidence for long-term treatment effects and hereby implications for practice.

4.4. Implication for practice

The strength of recommendations for clinical practice depends on the level of evidence as indicated by a risk of bias assessment (internal validity), on consistency of results between studies, and on generalisability (external validity). Based on the findings of this review, existing CPP clinical guidelines, textbooks on CPP and narrative reviews should be interpreted with caution. This because current recommendations for specific physiotherapy treatments are not evidence-based. That only small, single studies have been undertaken of most of these interventions greatly limits the available evidence on which clinical practice can be based. There seems to be some evidence to support Mensendieck somatocognitive therapy, and the use of a multidisciplinary intervention, but further work is required to confirm these findings.

4.5. Implication for further research

Given the prevalence and healthcare costs associated with female CPP methodologically robust primary research should be designed and conducted to test the effect of physiotherapeutic interventions for CPP. The clinically relevant levels of pain improvement demonstrated in the RCTs included in this systematic review should inform hypotheses for future high quality RCTs in order to reinforce the evidence base for physiotherapeutic interventions. The conduct of and critical appraisal of future RCTs should follow the CONSORT statement checklists and flow diagram [55], and refer to important outcome domains [56] and relevant length of treatment/time to follow-up. This would strengthen the provided evidence remarkably.

Conflict of interest

The authors declare no conflict of interest.

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