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CLINICAL PAPER

Efficacy of a therapeutic wand in addition to physiotherapy for treating bladder pain syndrome in women: a pilot randomized controlled trial

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Abstract

The aim of this study was to assess the feasibility of a randomized controlled trial (RCT) investigating the use of a therapeutic wand (TW) for pelvic floor muscle (PFM) treatment in women with bladder pain syndrome (BPS). Prolonged PFM tension contributes to the bladder pain, urinary frequency and urgency associated with BPS. Pelvic health physiotherapists routinely provide intravaginal myofascial release (MFR) to the PFMs in order to effectively reduce symptoms. Rapid access to physiotherapy during flare-ups of symptoms is effective, but difficult to obtain. A TW was designed so as to allow men with chronic pelvic pain to self-treat, and this may be effective in women with BPS. For 6 weeks, two groups received weekly physiotherapist-provided MFR, and were monitored for a further 6-week follow-up period. One group also used a TW at home three times a week throughout the pilot. Weekly outcome measures of BPS symptoms and quality of life were recorded. A clinically meaningful difference in Interstitial Cystitis Symptoms Index and Interstitial Cystitis Problem Index score changes between groups was recorded at 6 weeks (control group = 4.25 ± 0.95 and 3.50 ± 1.91, respectively; TW group = 6.20 ± 0.83 and 5.00 ± 1.41, respectively), and a difference was observed during the follow-up period (control group = 4.50 ± 1.73 and 4.00 ± 2.44, respectively; TW group = 8.00 ± 2.12 and 7 ± 1.87, respectively). There were no adverse events. Using the TW appears to have enhanced physiotherapy treatment during the initial 6 weeks, and improved symptoms during the 6-week follow-up period. The TW may be a clinically useful tool for long-term management of BPS. The feasibility of the study method was proven, some alterations were recommended and an RCT is now warranted.

Keywords: bladder pain syndrome, physiotherapy, self-treatment, therapeutic wand.

Introduction

Bladder pain syndrome (BPS) is an umbrella term for a poorly defined heterogeneous spectrum of chronic bladder conditions that form a subgroup of chronic pelvic pain (CPP) (Engeler *et al.* 2012). Sufferers experience pelvic pain without infection that worsens when the urinary bladder fills and eases with voiding, and also a persistent urge to void or an increase in frequency (Fall *et al.* 2010; Hanno *et al.* 2010). The prevalence of BPS is estimated to be 2.7–7.9% in women and 0.4–1.9% in men (Berry *et al.* 2011; Suskind 2013).

When the condition was initially described, it was thought to be associated with a persistent infection of the bladder lining because of the similarity in symptoms, and therefore, it was named "interstitial cystitis". However, cystoscopic bladder investigations of patients with BPS often find no infection, and hence, the umbrella term "bladder pain syndrome" was recently adopted to reflect patient experience more appropriately (Hanno *et al.* 2010).

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The aetiology of BPS is unclear, and is currently thought to involve an initial insult to the bladder that produces local inflammatory, neurological and endocrine responses that may develop into a systemic pain syndrome (Nickel *et al.* 2010). Other systemic, non-bladder conditions such as irritable bowel syndrome and fibromyalgia are known risk factors for the development of BPS, which suggests that there is a potential centrally driven predisposition to widespread hyperalgesia (Warren *et al.* 2011; Engeler *et al.* 2012). Changes occur in the activity of afferent nerves of the bladder lining, causing urinary urgency and frequency (Daly *et al.* 2011), and emotional responses to symptoms may promote local bladder neuropathic inflammation (Rapariz-González *et al.* 2014). Ultrasound assessment has revealed that the pelvic floor muscles (PFMs) also become less mobile and painful on palpation (Fall *et al.* 2010; Khorasani *et al.* 2012). Pastore & Katzman (2012) suggested that reduced mobility would prevent the PFMs from performing the reflex action needed to inhibit the bladder detrusor during filling, creating symptoms of urinary urgency and frequency. Quintner *et al.* (2014) proposed that both the altered mechanosensation and increased resting tension of the muscles are caused by focal neural inflammation, which may then be maintained centrally in BPS (Bove *et al.* 2003). Frawley (2015) suggested that this should be defined as PFM tension myalgia. Peters *et al.* (2007) found that bladder pain and urgency persist after bladder treatment for BPS if PFM palpation remains painful. This supports the notion that PFM pain, tension and bladder symptoms are linked.

Sufferers of BPS experience painful and regular flare-ups in their symptoms that can last for weeks or months (Sutcliffe *et al.* 2015b), and therefore, they remain constantly vigilant for potential triggers. This disrupts employment and social activities, reducing their quality of life (Rapariz-González *et al.* 2014; Sutcliffe *et al.* 2015a). The population with BPS have a higher incidence of depression, anxiety and insomnia than matched controls [risk compared to normal population (95% confidence interval) = 2.4 (2.2–2.6), 2.4 (2.2–2.7) and 2.1 (1.8–2.4), respectively; Chuang *et al.* 2015], and are known to exhibit poor illness coping strategies (Naliboff *et al.* 2015).

Limiting treatment to the bladder is ineffective, and therefore, international guidelines promote a multidisciplinary approach to symptom and disability management (Engeler *et al.* 2012; Hoffman 2015). Physiotherapy treatment aims to restore normal PFM tension and range of movement, desensitize muscle nociceptors, and promote optimal bladder and bowel function (Bø *et al.* 2015; Frawley 2015). Intravaginal PFM myofascial release (MFR) is a treatment that is routinely provided by pelvic health physiotherapists.

A literature search identified six studies of MFR of the PFMs in participants with BPS that were of appropriate methodological quality. Two further case series investigating MFR for chronic prostatitis ($n = 2$) (Van Alstyne *et al.* 2010) and women with CPP ($n = 6$) (Montenegro *et al.* 2010) were excluded from the analysis. Five studies reported a significant reduction in bladder pain, and urinary urgency and frequency (all $P \leq 0.025$) (Weiss 2001; Oyama *et al.* 2004; Anderson *et al.* 2005; FitzGerald *et al.* 2009, 2012). Chiarioni *et al.* (2010) found that MFR was less efficacious than biofeedback or electrical stimulation, but reported that it produced a significant ($P \leq 0.025$) reduction in pain intensity. These studies combined several conservative therapies, including relaxation and psychological coping strategies, and varied in the application of MFR techniques (see Table 6 in "Appendix 1"). While this makes it impossible to determine the optimal PFM manual therapy, a trend was observed for improved outcomes with MFR applied over a duration of at least 5 weeks and lasting more than 10 min per session, and using an individualized approach to the patient presentation that included some contract–relax stretching and sustained, gentle compression.

It is thought that MFR produces a cerebral and corticospinal analgesic response (Piché *et al.* 2009), modulates PFM nociceptors and mechanoreceptors (Chaitow 2007; Quintner *et al.* 2014), and improves resting PFM tension (Frawley 2015), allowing for reflex inhibition of the bladder during filling (Pastore & Katzman 2012). Accessing urgent physiotherapy treatment can quickly relieve symptoms, but this is difficult to obtain (Sutcliffe *et al.* 2015a), and symptom resolution can require a substantial, labour-intensive physiotherapy time commitment (Anderson *et al.* 2011a).

Anderson *et al.* (2011a) developed a therapeutic wand (TW) to allow patients with urological CPP to access their own PFMs and perform independent MFR. Several trials by the same clinical group on mostly male participants with CPP attending a US pelvic pain clinic have demonstrated the efficacy and safety of TW use (Anderson *et al.* 2011a, b, 2015, 2016; see Table 7 in

"Appendix 2"). A significant reduction was observed in the pelvic pain of 94% of patients ($P \leq 0.001$) using the TW three to four times a week for 4–6 months. However, the efficacy of the TW itself could not be determined because there was no control group for comparison, and the intervention included psychological strategies for improving coping, such as mindfulness. The observed improvements may suggest that the TW reproduces the suggested analgesic and neuromuscular modulating effects of physiotherapist-applied MFR (Piché *et al.* 2009; Frawley 2015).

Using a TW for MFR of PFM hypertonicity is routinely taught in specialist physiotherapy courses (e.g. Ruth Jones's "The Pelvic Detective Course: Physiotherapy Assessment and Treatment of Chronic Pelvic Pain", University Hospital of Wales, Cardiff, May 2014), and discussed in textbooks (Chaitow & Lovegrove Jones 2012) and patient self-help books (Wise & Anderson 2010; Herrera 2014). Patients' self-efficacy can be improved by providing them with self-management tools (Dufour *et al.* 2015), and this is known to improve their perception of pain and disability (Denison *et al.* 2004). Therefore, self-treatment is itself a powerful method of improving health outcomes (Bodenheimer *et al.* 2002), and alongside physiotherapy, the TW has the potential to enhance these for patients with BPS by increasing treatment frequency and allowing independent management of symptom flare-ups.

Despite the potential benefits of using the TW to manage BPS, further investigation is warranted since no identified studies have specifically investigated the utility or potential effect of a TW in women with BPS. The present pilot study aimed to test the feasibility of a randomized controlled trial (RCT) investigating the use of a TW in a sample of women with BPS.

Participants and methods

A volunteer sample of women diagnosed with BPS was drawn from urology and urogynaecology consultants at a Welsh private hospital. Each consultant reviewed the patients who had been identified against inclusion and exclusion criteria (see Box 1), and appropriate potential participants ($n = 37$) were sent a letter of invitation. Patients who responded to the invitation ($n = 23$, 62%) were invited to discuss participation; four declined and nine were excluded after further detailed comparison with the inclusion/exclusion criteria. Ten women consented to participate, and nine completed the study; one was excluded at the initial assessment because she had atrophic vaginitis. Participants underwent computer-generated block randomization into a control group and a TW group. Demographic characteristics were gathered for comparison with previous data. Randomization was not

Box 1. Participant inclusion and exclusion criteria: (TW) therapeutic wand; and (BPS) bladder pain syndrome

Inclusion criteria:
- females
- age 18–65 years (upper limit to reduce the risk of vaginal bleeding upon treatment with the TW) (Castelo-Branco *et al.* 2005)
- a diagnosis of BPS or interstitial cystitis as per the definition of the International Society for the Study of BPS (van de Merwe *et al.* 2008)
- symptoms of bladder pain, urgency and frequency in at least the last month prior to study participation
- pain on palpation of the pelvic floor muscles, as per the European Urology Association Bladder Pain Syndrome guidelines (Fall *et al.* 2010)
- ability to attend the department for treatment
- ability to give informed consent
- sufficient upper limb control to allow the participant to manipulate the TW for self-treatment

Exclusion criteria:
- concurrent diagnoses that may cause pelvic pain, including chronic pelvic inflammatory disease, endometriosis, dysmenorrhoea and irritable bowel syndrome (Alagiri *et al.* 1997)
- postmenopausal atrophic vaginitis because of the risk of vaginal trauma and bleeding with TW use (Castelo-Branco *et al.* 2005)
- reasonable suspicion of other treatable pathologies, such as urinary tract infection (van de Merwe *et al.* 2008)
- a lack of appropriate completed diagnostic investigations, such as urinalysis, or urodynamic or cystoscopic assessment, as per National Institute of Health and Care Excellence guidance (NICE 2013)
- pregnancy or planning to conceive
- symptoms associated only with menses (FitzGerald *et al.* 2009)
- undergoing concurrent treatments that could affect outcome, such as bladder Botox or analgesic injections, sacral neuromodulation, or physiotherapy treatment
- previous pelvic health physiotherapy treatment

Figure 1. The Premium TheraWand®: (left) handle; and (right) treatment end.

stratified because no evidence was identified for the effect of age, parity, duration of bladder symptoms, number of surgeries or analgesia use on MFR treatment response. No acceptable sham treatment exists since any intravaginal penetration potentially provides a therapeutic reduction in muscle tone (Weiss 2001), and therefore, participants were not blinded.

Standard multimodal physiotherapy assessment and treatment for BPS, including 15 min of PFM MFR (CSP 2012; Engeler *et al.* 2012), was provided weekly to both groups for 6 weeks by a single, experienced specialist pelvic health physiotherapist within a private hospital clinic setting (for details, see Fig. 1 and Table 1).

At the first session, the TW group each received a TW information sheet (see Fig. 6 in "Appendix 3"), and were taught how to use the TW safely for 15 min, three times a week, between each physiotherapy session and during the 6-week follow-up period. Both groups were instructed to carry out daily PFM active release exercises in sitting or standing during the 12-week study period. The primary outcome measures recorded weekly were the O'Leary–Sant Interstitial Cystitis Symptom Index (ICSI) and Interstitial Cystitis Problem Index scores (ICPI), and secondary measures of genital-pain-related quality of life, PFM pain on palpation, overall pain, and urinary urgency and frequency were also gathered. The TW group also completed a 3-month compliance diary. Participants returned after a further 6-week follow-up period for reassessment.

The Premium TheraWand® (Fig. 2) is made from medical-grade acrylic approved by the US Food and Drug Administration, is available in the UK, and the manufacturer (Pelvic Therapies, Inc., Carlsbad, CA, USA) provides quality and safety assurances. It is the same width as a finger (1.5 cm) and is 21 cm long, with only the first third being used internally for treatment.

Ethical approval for the present study was gained from the University of Bradford and the National Health Service Research Ethics Committee, and it was registered with ClinicalTrials.gov (NCT02743962).

Data analysis

In the proposed RCT, inferential statistics would be applied as appropriate to infer statistical significance from the data collected (Bowling 2014). However, this has little power with small

Table 1. Details of the standard physiotherapy treatment provided to both intervention groups in the first 6 weeks of the study (Bø *et al.* 2015; Frawley 2015): (PFMs) pelvic floor muscles; and (BPS) bladder pain syndrome

Treatment	Frequency
Education regarding female internal and external pelvic anatomy, the PFMs, and the pathology of BPS	Initial assessment/treatment session only
Education regarding correct PFM contraction for urinary urge suppression from the posterior to anterior muscles; education provided in sitting (clothed), then participants were guided to produce a correct contraction (if able) during PFM assessment	Repeated during each treatment session as required
Correct defecation dynamics position, low force and diaphragmatic breathing to achieve defecation	Initial assessment/treatment session, sheet also provided for reference; reviewed and reinforced during the initial 6-week treatment period as required
Bladder retraining information, including urge suppression, trigger avoidance and voiding timing	As above
Dietary fluid and fibre intake information	As above
Mindfulness relaxation	As above
Myofascial release of the PFMs: after initial PFM assessment, gentle compression was applied at 5 o'clock and 7 o'clock on the horizontal axis, then contract–relax stretching throughout the PFMs focusing on areas of tension and pain, followed by sweeps from origin to insertion; treatment was always determined by participant presentation, but loosely followed this structure	15 min weekly for 6 weeks

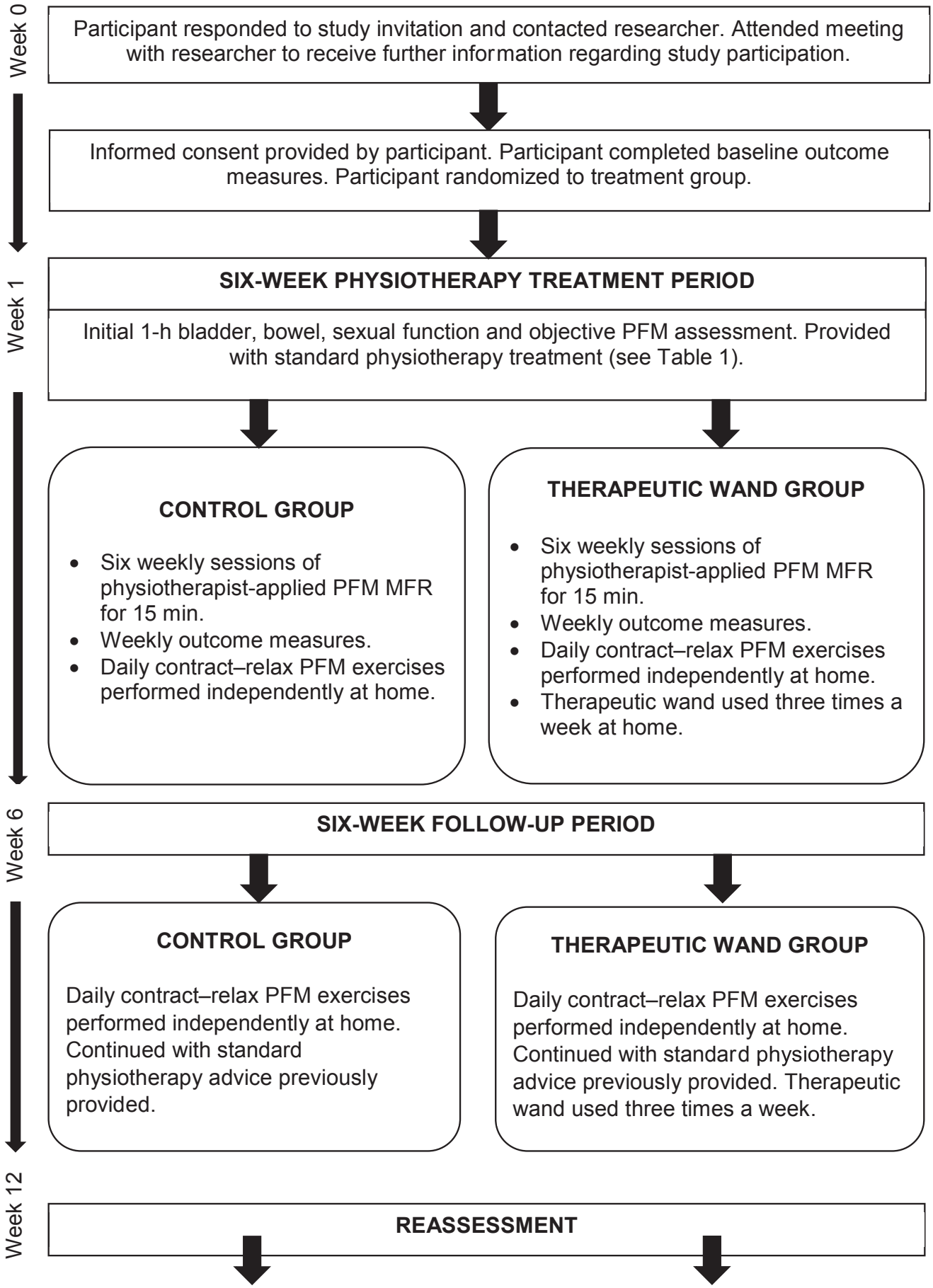

Figure 2. Flow chart of the study intervention: (PFM) pelvic floor muscle; and (MFR) myofascial release.

Table 2. Clinical significance standards for each outcome measure: (MCID) minimal clinically important difference; (ICSI) O'Leary–Sant Interstitial Cystitis Symptom Index; (ICPI) O'Leary–Sant Interstitial Cystitis Problem Index; (GUPI) Genitourinary Pain Index; (PUF) Pelvic Pain and Urinary Urgency Frequency Patient Symptom Scale; (VAS) visual analogue scale; and (NRS) Numerical Rating Scale

Outcome measure	MCID standard	Reference
ICSI and ICPI	–4 points = moderate improvement –7 points = great improvement –9 points = symptom resolution	Lubeck *et al.* (2001)
GUPI	–4 points = MCID –7 points = treatment responder	Clemens *et al.* (2009)
PUF	Reduction of 0.5 of one standard deviation	Norman *et al.* (2003)
VAS	–10 mm	Bourdel *et al.* (2015)
NRS for pelvic floor muscle palpation and therapeutic wand use	–5 points = very effective –2 points = moderately effective –1 point = not effective	Anderson *et al.* (2011a)

sample sizes, and would produce unreliable findings (Peat & Barton 2005; Ghasemi & Zahediasl 2012). Therefore, data analysis was conducted using descriptive statistics and compared with the known minimal clinically important differences (MCIDs) for each outcome measure (see Table 2) to inform examination of the trends observed (Peat & Barton 2005). For data analysis purposes, the patient-reported outcome measures used were considered to be interval data because these have been demonstrated to employ a ratio scale, and therefore, interval scale properties (Price *et al.* 2012); hence, mean scores and standard deviations are presented.

Results

All nine participants completed the study, and no adverse events were reported. The participants' mean age, parity, self-reported duration of symptoms, analgesia use and number of surgeries were sufficiently similar between the groups for them to be considered suitably homogeneous at baseline (see Table 1). Baseline symptom scores in the TW group (ISCI = 12.4 ± 2.07, ICPI = 11.20 ± 3.91) were higher than in the control group (ICSI = 10.50 ± 2.65, ICPI = 10.00 ± 2.68), although not by enough to constitute a clinically meaningful difference.

The demographic and symptom profiles of the control and TW groups are shown in Table 3.

Both groups demonstrated a trend for a reduction in ICSI and ICPI scores from baseline to week 12, with most of the improvement being observed between baseline and week 2 (ISCI change: control group = 3.75 ± 2.06, TW group = 4.00 ± 1.00; ICPI change: control group = 3.50 ± 1.29, TW group = 3.60 ± 1.67) (Table 4 and Figs 3 & 4). During the initial 6-week physiotherapy treatment period, both groups achieved improvements in all outcome measures to a level reaching the MCID. The change in score in the TW group was higher than in the control group, although the difference between the groups did not reach the MCID (ICSI change: control group = 4.25 ± 0.95, TW group = 6.20 ± 0.83; ICPI change: control group = 3.50 ± 1.91, TW group = 5.00 ± 1.41).

Table 3. Demographic and symptom profile for the control and therapeutic wand groups

			Prescription		
Age (years)	Parity	Symptom duration (years)	Analgesic drugs	Antimuscarinic drugs	Number of surgeries
Control group					
49	2	10	Nil	Solifenacin	2
54	0	4	Naproxen	Nil	1
18	0	1	Gabapentin and paracetamol	Nil	0
24	0	2	Amitriptyline	Oxybutynin	0
Therapeutic wand group					
26	1	11	Gabapentin	Solifenacin	1
27	0	7	Paracetamol	Oxybutynin	1
36	2	2	Pregabalin	Nil	0
31	1	1	Nil	Nil	0
43	2	5	Paracetamol and gabapentin	Darifenacin	0

Table 4. Change in ICSI and ICPI scores over the duration of the study in the control and therapeutic wand (TW) groups: (SD) standard deviation; (ICSI) O'Leary–Sant Interstitial Cystitis Symptom Index; and (ICPI) O'Leary–Sant Interstitial Cystitis Problem Index

	Change in score (mean ± SD)				
Outcome measure	0–2 weeks	2–6 weeks	0–6 weeks	6–12 weeks	0–12 weeks
ICSI:					
control group	3.75 ± 2.06	0.50 ± 1.29	4.25 ± 0.95	0.00 ± 0.95	4.25 ± 1.73
TW group	4.00 ± 1.00	2.20 ± 1.09	6.20 ± 0.83	1.80 ± 1.73	8.00 ± 2.12
ICPI					
control group	3.50 ± 1.29	0.00 ± 0.80	3.50 ± 1.91	0.25 ± 1.29	3.75 ± 2.44
TW group	3.60 ± 1.67	1.40 ± 0.89	5.00 ± 1.41	2.00 ± 0.70	7.00 ± 1.87

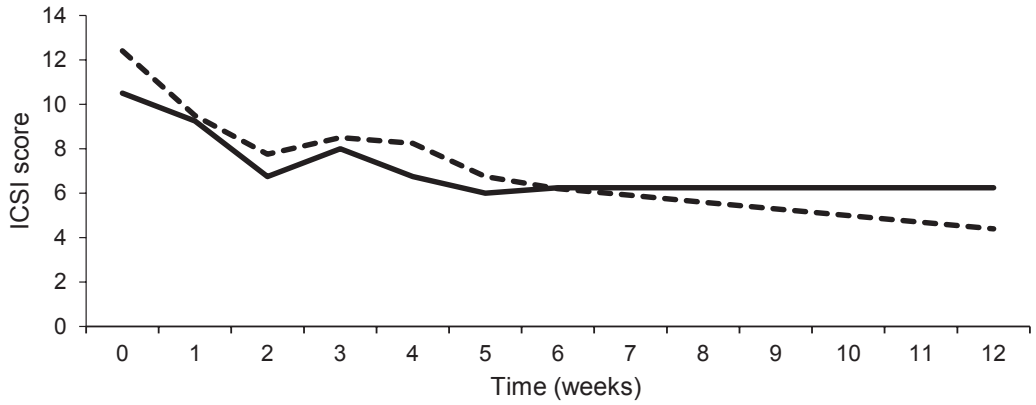

Figure 3. Line graph showing the participant mean O'Leary–Sant Interstitial Cystitis Symptom Index (ICSI) score change over the duration of the study in the control (—) and therapeutic wand (----) groups.

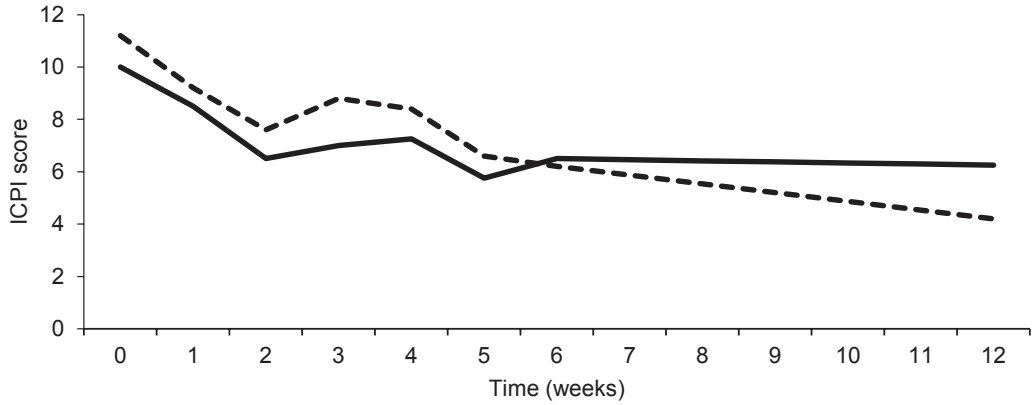

Figure 4. Line graph showing the participant mean O'Leary–Sant Interstitial Cystitis Problem Index (ICPI) score change over the duration of the study in the control (—) and therapeutic wand (----) groups.

During the 6-week follow-up period, the mean ICSI and ICPI scores continued to reduce in the TW group (ICSI change = 1.80 ± 1.73, ICPI change = 2.00 ± 0.70), whereas the control group plateaued (ICSI change = 0.00 ± 0.95, ICPI change = 0.25 ± 1.29). The secondary measures reflected this trend throughout (see Table 5).

From baseline to week 12, both groups had a reduction in ICSI and ICPI scores that met the MCID (four points) in all but the control group ICPI score change (3.75 ± 2.44). The TW group had twice the score change of the control group (see Table 4). Again, this trend was repeated in all the secondary measures, where the overall change in the TW group was greater than in the control group. There was a clinically significant difference between the score changes reported by the TW and control groups after 12 weeks of intervention.

When classified as treatment responders on the basis of the change in their ICSI score after 12 weeks, the control group was split between the bottom two levels (non-responder, $n = 1$; moderately improved, $n = 3$), whereas the TW group were all classified as being in the top two (greatly improved, $n = 3$; symptom resolution, $n = 2$). At 12 weeks, the utility of the TW was categorized by change in Numerical Rating Scale

Table 5. Mean baseline and mean change in secondary outcome measure scores over the course of the study in the control and therapeutic wand (TW) groups: (SD) standard deviation; (GUPI) Genitourinary Pain Index; (PUF) Pelvic Pain and Urinary Urgency Frequency Patient Symptom Scale; (VAS) visual analogue scale; (NRS) Numerical Rating Scale; and (PFM) pelvic floor muscle

		Change in outcome measure score (mean ± SD)†		
Outcome measure	Baseline score (mean ± SD)	0–6 weeks	6–12 weeks	0–12 weeks
GPI:				
control group	27.00 ± 7.07	**9.25** ± 4.85	1.25 ± 0.95	**10.50** ± 4.04
TW group	31.00 ± 4.89	**11.60** ± 5.50	3.40 ± 1.51	**15.00** ± 6.25
PUF:				
control group	14.00 ± 3.56	**3.75** ± 1.70	0.75 ± 0.96	**4.50** ± 2.64
TW group	16.20 ± 1.64	**6.80** ± 1.79	**2.20** ± 1.30	**9.00** ± 2.83
VAS* (urgency):				
control group	60.00 ± 18.25	**20.00** ± 8.16	**10.00** ± 8.16	**30.00** ± 8.16
TW group	70.00 ± 21.21	**42.00** ± 8.36	6.00 ± 5.48	**48.00** ± 13.03
VAS* (bladder pain):				
control group	57.50 ± 15.00	**22.50** ± 5.00	2.50 ± 0.50	**25.00** ± 10.00
TW group	68.00 ± 17.50	**42.00** ± 16.43	4.00 ± 5.48	**46.00** ± 16.73
VAS* (overall pain):				
control group	57.50 ± 15.00	**25.00** ± 12.91	2.50 ± 9.57	**27.50** ± 9.57
TW group	66.00 ± 20.70	**30.00** ± 12.25	8.00 ± 8.37	**41.00** ± 16.43
NRS for PFM pain:				
control group	7.25 ± 1.50	**4.75** ± 1.50	0.25 ± 0.50	**5.00** ± 1.41
TW group	8.00 ± 0.70	**6.00** ± 1.22	1.20 ± 1.09	**7.00** ± 0.45

*Scores in millimetres.
†Results in boldface type signify changes greater than the minimally clinically important difference in score.

(NRS) pain on palpation scores, and all participants were within the very effective bracket ($n = 5$). There was good compliance with use of the instrument in the TW group, with a median frequency of two times a week throughout the study.

Discussion

The baseline characteristics of the sample were similar to those that have previously been reported, and both the control and TW groups' mean ICSI (10.5 and 12.4, respectively) and ICPI (10.0 and 11.2, respectively) scores were similar and within one standard deviation of previous studies (ICSI = 13.0 ± 4.8, ICPI = 12.1 ± 3.3, FitzGerald *et al.* 2009; ICSI = 11.4 ± 3.5, ICPI = 10.7 ± 3.0, FitzGerald *et al.* 2012). Therefore, the groups were considered representative of the wider population with BPS and suitably homogeneous at baseline.

For all outcome measures, the greatest improvement was observed in the first 2 weeks of treatment, with both groups achieving a change in score that almost met the MCID (4) for the ICSI and ICPI score changes (control group: ICSI = 3.35 ± 2.06, ICPI = 3.50 ± 1.29; and TW group: ICSI = 4.0 ± 1.0, ICPI = 3.60 ± 1.67). This finding supports previous evidence indicating that the standard multimodal physiotherapy intervention for BPS can quickly provide a clinically meaningful reduction in bladder pain, urinary urgency and frequency, quality of life, and PFM pain (Weiss 2001; Oyama *et al.* 2004; Anderson *et al.* 2005; FitzGerald *et al.* 2009, 2012; Chiarioni *et al.* 2010). However, despite the difference in the frequency of MFR treatment in the first 2 weeks of the intervention (the control group received two, and the TW group received a mean of six when TW use was included), the change in symptoms was similar between groups. This raises the possibility that using a TW provides no advantage over standard multimodal physiotherapy in the initial treatment period, or that the rate of symptom improvement has a ceiling. Since the only comparative data for TW use was recorded monthly, the importance of this finding is unknown (Anderson *et al.* 2011a, b, 2015). It is important that this is further investigated to ascertain when the TW may potentially influence treatment response in order to decide the frequency of outcome measures recorded, and to provide clinical guidance in any adjunctive TW use in this population.

It has been suggested that MFR modifies the peripheral nociceptors and mechanoreceptors that produce spontaneous pain, further neuroinflammation and hypersensitivity (Quintner *et al.* 2014) by improving localized venous congestion and reducing muscular tension (Chaitow 2007). A reduction in pain was observed in both groups after 2 weeks, which suggests that desensitization of the PFMs had occurred (NRS PFM pain

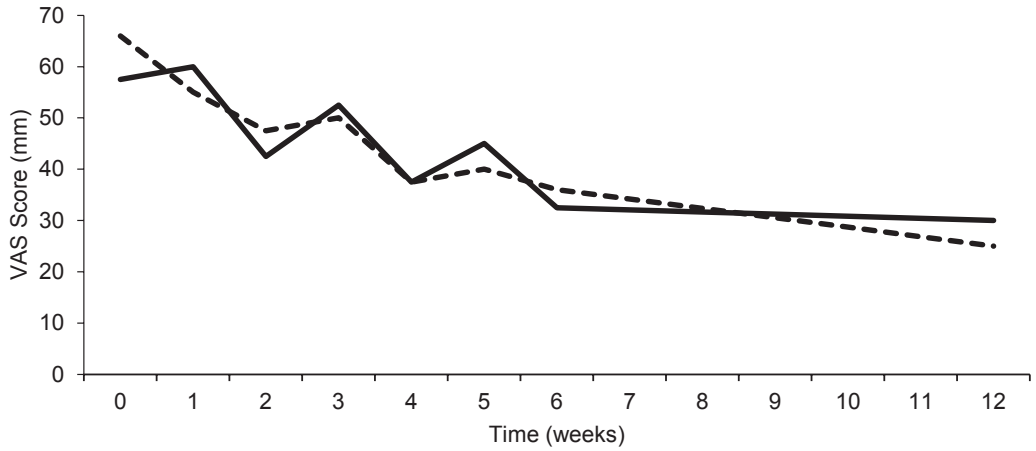

Figure 5. Line graph showing the participant mean visual analogue scale (VAS) score for overall pain over the duration of the study in the control (—) and therapeutic wand (----) groups.

change: control group = –1.5, TW group = –2.0). This supports previous studies demonstrating a significant reduction in PFM pain (Oyama *et al.* 2004; FitzGerald *et al.* 2009, 2012; Chiarioni *et al.* 2010).

A competing counterirritation stimulus, such as that produced by palpating painful muscle tissue, has been shown to activate cortical processes, producing a descending modulation of spinal nociception and an analgesic response (Piché *et al.* 2009). This may explain the observed concurrent reduction in bladder, pelvic floor and overall pain recorded in both groups after 2 weeks of treatment (GUPI change: control group = 6.75, TW group = 7.25; VAS bladder pain change: control group = 1.75, TW group = 3.05; VAS overall pain change: control group = 1.50, TW group = 1.85; see Fig. 5). However, this could also be a result of central desensitizing elements of the multimodal treatment, such as PFM release exercises or mindfulness relaxation.

Symptom flare-ups were observed in both groups during the initial 6-week treatment period, and declined in intensity over time. It may be theorized that flare-ups are a normal part of the initial rehabilitation process, which would be an important clinical observation of the present study; BPS flare-ups were observed after treatment commenced, which was not expected, and the treatment provided then improved the flare-up intensity over time. This is in keeping with the reported patient experience that physiotherapy treatment reduces flare-up intensity quickly (Sutcliffe *et al.* 2015b), and further investigation is required to observe the natural progression of any symptom flare-ups with physiotherapy treatment.

After 6 weeks of physiotherapy treatment, the TW group demonstrated a greater reduction in all symptom and bother scores than the control group, and the difference between groups was at least a further half of the MCID score (Tables 4 & 5). The change in the control group was comparable to those of FitzGerald *et al.* (2012) (score change: ICSI = 3.2 ± 3.7, ICPI = 3.6 ± 3.6, $P = 0.0012$ for both), as would be expected of a similar intervention. However, the difference in ICSI score achieved by the TW group at 6 weeks was double that of the physiotherapist-applied MFR in the FitzGerald *et al.* (2012) study after 10 weeks. This finding further shows the potential for TW use to enhance treatment response by increasing the frequency of MFR treatment.

The present findings support those of previous studies, which found that an individualized approach to MFR treatment involving vaginal access to the PFMs with contract–relax stretching is effective (significant reduction in pain, all $P \leq 0.025$; Weiss 2001; Anderson *et al.* 2005; FitzGerald *et al.* 2009, 2012). Because this technique was used for both the manual, physiotherapist-applied and TW MFR, TW use may have increased the frequency of treatment. It has been suggested that gentle contract–relax stretching creates presynaptic ischaemic muscle inhibition, and produces immediate passive muscle lengthening (Beltrão *et al.* 2014). This may increase the functional movement of the PFMs (Khorasani *et al.* 2012), allowing for neurogenic reflex inhibition of the detrusor muscle during filling (Pastore & Katzman 2012). Theoretically, this would produce a concurrent improvement in urinary urgency and frequency, as was observed in the present study, and therefore, this warrants replication in a larger trial to further assess this possibility. Thus, an improvement in PFM resting tension and pain could be said to bring about functional improvements in participants' bladder

symptoms (ICSI change: control group = 4.25, TW group = 6.2; Pelvic Pain and Urinary Urgency Frequency Patient Symptom Scale change: control group = 3.75, TW group = 6.8), and TW use may have amplified the change in symptoms observed by increasing the frequency of PFM treatment.

A trend for continuing improvement in the TW group and a plateau in the control group during the follow-up period was observed across all the outcome measures (see Tables 4 & 5), and this appears to be a novel finding. Anderson *et al.* (2011a) only recorded monthly measures during a more-intense intervention that varied too much from the current protocol for a comparison to be made. The repeated measures recorded in the present study hint at the potential for clinically useful information to be gleaned from more-frequent assessment during the study period, and a longer follow-up duration would also allow for further extrapolation of any difference between the TW and control groups in the efficacy of their self-management.

Kaptchuck *et al.* (2000) discussed the potential of a heightened placebo response to medical devices, as observed with sham acupuncture and transcutaneous electrical nerve stimulation machine use, where a baseline placebo response to a device may impact the observed results and lead to misinterpretation. In the present study, participants may have had a placebo-driven response to TW use. A further investigation could consider a third TW control group to assess for this effect: participants could be provided with a TW and taught only external pelvic massage.

The continued improvement observed in the TW group after the physiotherapist-applied MFR was discontinued at 6 weeks is an important finding of the present research. While a larger-scale study is required to corroborate this finding, a sound theoretical basis for the mechanism by which the TW may improve outcomes exists. Providing participants with the ability and knowledge to change their symptoms may, in itself, have improved their reported pain and disability, and may account for the continued score changes during the follow-up period. Self-efficacy is known to be enhanced by improving patients' perceptions of their control of their health status (Dufour *et al.* 2015): it provides an internal motivation to self-manage symptoms (Anderson *et al.* 2002), and in turn, this is known to improve outcomes (Bodenheimer *et al.* 2002). In patients with musculoskeletal pain, self-efficacy is the most important element of how they determine their disability (Denison *et al.*2004), and Blyth *et al.* (2004) found that active self-management reduces the likelihood of pain-related disability (adjusted odds ratio = 0.2).

The TW also represents a potential BPS self-management strategy, giving sufferers the opportunity for timely treatment of their symptom flare-ups instead of waiting for a physiotherapy appointment. The prevalence of sexual abuse is known to be slightly higher in those with BPS than in the general population (Warren *et al.* 2011), and undergoing regular intravaginal treatment has the potential to unlock experiences or to create distress (Peters 2010). Therefore, patients who are averse to hospital-based intravaginal treatment or unable to attend it would be able to access treatment independently in their own home by using a TW, reducing the need for potentially embarrassing or distressing internal treatment at the physiotherapy clinic. Promoting the concurrent use of a TW may also reduce the burden on stretched physiotherapy services, which previously had to provide the required labour-intensive treatment by reducing the necessary treatment duration. There is also the potential for physiotherapist contact to reduce as patients become proficient in their own self-management with TW use, changing the therapist's role to that of a guide to self-management, providing manual therapy only to those who are struggling with self-management. Therefore, the potential for patients to have access to enhanced physiotherapy intervention and effective self-treatment, and the possibility of a reduction in the demand on physiotherapy services warrants further investigation.

Limitations

The implications of the findings reported in the present study are unclear because the small sample allowed only limited data analysis. Volunteer sampling may have skewed the results towards those willing to self-treat with a TW, as shown by the high compliance with TW use. Therefore, the acceptability of independent intravaginal treatment requires further investigation. Exclusion of non-bladder conditions known to be risk factors for BPS development may have overtly limited the sample, and therefore, the generalizability of the findings to the wider population with BPS. The lack of assessor blinding was a pragmatic step to ensure participant safety in a small pilot, and this may have influenced the results.

Feasibility

The methods trialled proved to be feasible and safe, and some modifications are suggested for an RCT. Collaboration over multiple sites should be used to recruit a sufficiently large sample, which was prolonged in the present single-site pilot. Prospective convenience sampling from clinics would improve the rate of recruitment, and also reduce the bias of a motivated volunteer sample. Assessing vaginal resting tone and PFM movement would improve the understanding of underlying treatment mechanisms. Assessor blinding should be used to improve study validity.

Conclusions

The present pilot study has demonstrated that the RCT method is feasible.

Using a TW twice weekly appears to be a useful clinical adjunct to physiotherapy treatment. Both groups achieved a clinically meaningful change in symptom score during the initial treatment period that was maintained at follow-up. However, the use of a TW appears to have enhanced the physiotherapy treatment received, and improved the maintenance of therapy gains during the follow-up period. It is unknown whether this was because of the increased frequency of MFR treatment received by those using a TW, or reflects a potential treatment effect of the TW, an improvement in physiotherapy treatment carryover or the effect of improving participants' locus of control for their health status.

The findings of the present study suggest that the TW may provide a suitable and safe self-management tool for patients suffering from BPS. This would potentially give sufferers the opportunity for timely treatment of symptom flare-ups instead of having to wait for a physiotherapy appointment. Patients who are averse to hospital-based intravaginal treatment or unable to attend it would have the option of accessing the known benefits of PFM MFR independently in their own home, and the pressure on stretched physiotherapy departments to provide labour-intensive treatment might be reduced.

The feasibility of conducting an RCT investigating the use of a TW in women with BPS has been demonstrated, and some areas where the method could be adapted have been highlighted. Caution must be applied so as not to infer significance in the findings of the present small pilot study. However, the clinically meaningful changes observed warrant further examination with an appropriately powered RCT given the potential benefits to the quality of life experienced by those living with BPS. Further qualitative investigations of the lived experience of women self-managing the symptoms of BPS using a TW are also required to ascertain the acceptability, and therefore, clinical benefit and impact of using a TW.

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Appendix 1

Table 6. Summary of evidence for manual myofascial release in pelvic pain: (RCT) randomized controlled trial; (PFM) pelvic floor muscle; (IBS) irritable bowel syndrome; (BPS) bladder pain syndrome; (NIH-CPSI) National Institutes of Health Chronic Prostatitis Symptom Index; (IC) interstitial cystitis; (MFR) myofascial release; (BFB) biofeedback training; (NMES) neuromuscular electrical stimulation; (GTM) global therapeutic massage; (GRA) global response assessment; (UCPP) urological chronic pelvic pain; (ICSI) O'Leary–Sant Interstitial Cystitis Symptom Index; (ICPI) O'Leary–Sant Interstitial Cystitis Problem Index; (VAS) visual analogue scale; (MPT) myofascial physical therapy; and (SF-12) 12-Item Short Form Health Survey

Reference	Type of study	Sample	Intervention	Control	Assessment	Findings
Anderson *et al.* (2005)	Case series ($n = 138$ men)	Chronic pelvic pain refractory to traditional therapy Pain on PFM palpation	MFR weekly for 4 weeks, then biweekly for 8 weeks Paradoxical relaxation for 1 h a day 12 sessions over 20 weeks	None	Monthly for 6 months	69% had a clinical improvement in pain of > 50% at 3.4 months GRA: 72% of patients improved Reductions in pain ($P = 0.001$) and urinary symptoms ($P \leq 0.001$)
Chiaroni *et al.* (2010)	RCT ($n = 157$)	Chronic or recurrent rectal pain for > 12 weeks Aged 18–70 years Excluded if met Rome II IBS criteria	MFR: three, 20-min sessions a week for 3 weeks BFB: five sessions of 30 min NMES: nine, 30–45 min sessions	Three-group comparison	Baseline, and follow-up at 1, 3 and 6 months	"Adequate relief": BFB = 87%, NMES = 45%, MFR = 22% Pain intensity reduction: 5 BFB, 2.1 NMES, 0.8 MFR (all $P \leq 0.025$)
FitzGerald *et al.* (2009)	Multicentre RCT feasibility trial ($n = 44$)	Aged 18 years or older Women with a clinical diagnosis of BPS Males with a NIH-CPSI score of > 15 Pain on PFM palpation	MFR targeting pelvic floor, hip girdle and abdominal muscles: 1 h a week for 10 weeks	GTM: 1 h of full-body Western massage a week for 10 weeks	Pre- and post-treatment, and follow-up at 3 months	GRA: MFR = 57% and GTM = 21% ($P = 0.03$) In BPS, significant relief of PFM pain with MFR ($P \leq 0.001$) over global massage Women with BPS responded better to MFR than men (UCPP)
FitzGerald *et al.* (2012)	Multicentre RCT ($n = 88$ women)	Women with a diagnosis of BPS PFM pain Previous failed treatment From 3 months to 3 years in duration	MFR targeting pelvic floor, hip girdle and abdominal muscles: 10×60 min over a 12-week period	GTM: 1 h of full-body Western massage a week for 10 weeks	Pre- and post-treatment, and follow-up at 3 months	59% and 26% in the MPT and GTM groups, respectively, reported improvement (responders: $P = 0.0012$)
Oyama *et al.* (2004)	Uncontrolled clinical trial ($n = 21$)	Diagnosis of IC/BPS High PFM tone on palpation Aged 18 years or older	MFR: 5 min twice a week for 5 weeks	None	Pre- and post-treatment, and follow-up at 4.5 months	Significant improvement in ICSI ($P = 0.015$) and ICPI ($P = 0.039$) scores Reduction in VAS scores for urgency and pain ($P = 0.001$ and $P = 0.005$) SF-12 ($P = 0.042$)
Weiss (2001)	Uncontrolled clinical trial ($n = 52$)	Pelvic pain BPS/frequency–urgency syndrome Failed medical treatment	MFR: once or twice a week for 8–12 weeks (until tenderness abated) PFM release exercises at home Relaxation	None	Pre- and post-treatment	Marked (31%) and moderate (31%) improvements in urgency–frequency symptoms Complete resolution (21.4%)

Appendix 2

Table 7. Summary of the evidence for therapeutic wand use in pelvic pain: (PFM) pelvic floor muscle; (NIH-CPSI) National Institutes of Health Chronic Prostatitis Symptom Index; and (GRA) global response assessment

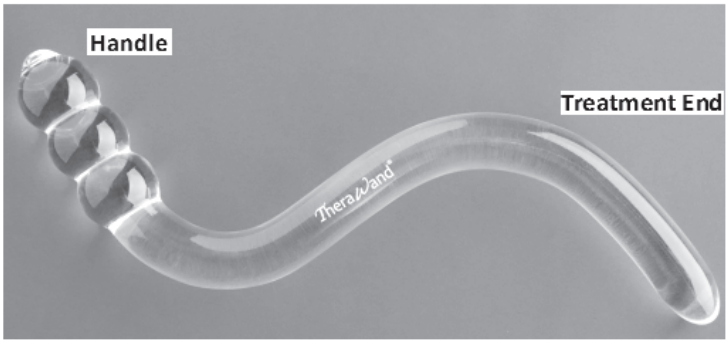
Reference	Participants	Sample	Intervention	Control	Assessment	Findings
Anderson *et al.* (2011a)	Men and women ($n = 113$)	Men and women who self-referred Chronic pelvic pain Pelvic pain on palpation Competent in therapeutic wand use	Initial 6-day intensive multimodal treatment for 3–5 h a day Therapeutic wand use for 5–10 min three or four times a week PFM relaxation exercises daily	None	Baseline, and follow-up at 1 and 6 months	No major adverse events Significant reduction in PFM pain at 1 ($P \leq 0.001$) and 6 months ($P \leq 0.001$) 95% reported that treatment was very ($n = 44$) or moderately ($n = 62$) effective for alleviating pain
Anderson *et al.* (2011b)	Men and women ($n = 116$)	As above	As above	None	Baseline, and follow-up at 4–23 months	Significant improvement in pain, urinary dysfunction and quality of life post-treatment (all $P \leq 0.001$) maintained at 4–23 months GRA: 59% of patients showed marked to moderate improvement
Anderson *et al.* (2015)	Men and women ($n = 396$, 79.7% male)	As above	As above	None	Baseline, and follow-up at 1 and 6 months	Significant reduction (36.9%) in medication usage at 6-month follow-up ($P \leq 0.001$) Medication cessation at 6 months significantly associated with total symptom reduction ($P = 0.03$)
Anderson *et al.* (2016)	Men and women ($n = 393$, 79.9% male)	As above	As above	None	As above	Male baseline NIH-CPSI score lower than female one ($P = 0.04$) No difference between genders at 6 months in PFM pain ($P = 0.1$), total symptom reduction ($P = 0.8$) or emotional distress ($P = 0.19$)

Appendix 3

The information sheet that the TW group was provided with is shown in Fig. 6.

Instructions for Therapeutic Wand Use at Home

- Think of your pelvic floor as a clock, where the clitoris is at 12 o'clock and the back passage is at 6 o'clock. The wand should **never** be used in the areas marked red on the diagram as the tube from your bladder is between 11 and 1 o'clock and your bowel is between 5 and 7 o'clock.



- Lying on the bed or in the bath assume a comfortable, supported position with your knees bent. If lying on the bed, liberally cover the end of the wand with lubricant, this is not always required if using in the bath. Holding the bobbled end, insert the other end of the therapeutic wand into your vagina.

- To identify tender areas in your pelvic floor muscle start by performing a few gentle sweeping strokes between 5 and 1 o'clock and then at 7 to 11 o'clock as deep as the first curve of the wand. Then withdraw the wand a little and repeat the sweeps with just the tip. Any areas that are exquisitely tender and refer pain somewhere else in your pelvis region when pressed are likely to be trigger points.

- Sustain a moderate pressure to a trigger point for 10 seconds, then contract the pelvic floor muscle and release fully a few times, using the therapeutic wand to guide the muscle downwards. After this a comfortable stretch using the wand should be applied for 10 seconds. This should be repeated until all trigger points have been released, and should take between 5 and 10 minutes.

- If tingling or extreme pain occurs on trigger point massage discontinue and move to another area. Occasionally pain may occur after wand use but this should not persist for more than an hour. If you are concerned contact the researcher on the phone number provided. Do not use the therapeutic wand if you have an infection or vaginal bleeding with wand use.

Therapeutic Wand Cleaning

- Use warm water and a clean towel to clean the therapeutic wand after each use.
- Soap is not necessary and may produce vaginal irritation.
- Do not apply alcohol gel or any cleaning product containing alcohol onto the therapeutic wand.
- Store the wand in the pouch provided between uses.

Figure 6. Information sheet given to the therapeutic wand group.