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CLINICAL ARTICLE

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Efficacy of capacitive resistive monopolar radiofrequency in the physiotherapeutic treatment of chronic pelvic pain syndrome: A randomized controlled trial

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Abstract

Aim: To evaluate the efficacy of adjuvant, capacitive resistive monopolar radiofrequency (CRMRF, INDIBA) treatment at 448 kHz together with physiotherapeutic techniques compared to a sham treatment with the same techniques, for pain reduction and quality of life (QoL) improvements in patients with chronic pelvic pain syndrome (CPPS).

Methods: A triple-blind, randomized controlled trial (RCT) including patients with CPPS randomly allocated (1:1) to a CRMRF-activated group (intervention) or a CRMRF-deactivated one (control). Both groups received physiotherapeutic techniques and pain education weekly for 10 consecutive weeks. Data from a visual analogical scale and the SF-12 questionnaire were collected at trial commencement and repeated at the 5th and 10th sessions. Pain intensity was considered the main outcome. For the comparisons between variables, the χ^2 and Student's t test were used. Superiority was analyzed by estimating the mean change (95% confidence interval). Analysis was performed for the per-protocol and the intention-to-treat populations. The statistical significance level was set at $p < 0.05$.

Results: Eighty-one patients were included (67.9% women) with a mean age of 43.6 years (SD 12.9). CRMRF lessened pain scores by more than 2 points and improved QoL by 5 points. There were no relevant side effects and overall adherence to the treatment was 86.4%.

Conclusions: This is the first RCT that evaluates the efficacy of CRMRF (INDIBA) compared to a sham treatment, and demonstrates its superiority in decreasing pain and improving QoL. Such results may lead to greater prescribing of CRMRF when treating CPPS patients.

KEYWORDS
bladder pain syndrome, capacitive resistive monopolar radiofrequency, chronic pelvic pain, genital pain, INDIBA, pain, quality of life, randomized controlled trial, therapeutic interventions

1 | INTRODUCTION

Chronic pelvic pain syndrome (CPPS) affects a considerable number of individuals with a prevalence ranging from 5.7% to 26.6% in women and 2.2% to 9.7% in men.[1,2] In addition to causing urinary and genital functional disability, this multifactorial condition can have a marked impact on quality of life (QoL) including psychological well-being leading to social isolation.[3]

With respect to therapeutic approaches, there are various well-established physical options[4] including capacitive resistive monopolar radiofrequency (CRMRF). Considered a noninvasive therapy, this procedure increases the temperature of deep pelvic structures by employing low-frequency electromagnetic currents (448 kHz). Even though this clinical approach has been common practice for the last two decades, reliable clinical data concerning its use are lacking. It has been observed that the electromagnetic field generated by the current leads to vasodilatation and an increase in cellular activity, which helps the connective tissue repair process, improves its elasticity, and increases the pain threshold as it reduces inflammation.[5,6]

Thermal stimulation affects pain reduction by suppressing ischemia and spasticity. Stimulation of the temperature receptors augments vasodilation and alleviates pain due to ischemia.[7,8] In addition, the bioelectrical effect encourages local pain sensory thresholds to recover to normal levels. Such an analgesic effect can be explained by Melzack and Wall's Gateway Theory.[9] According to these authors, pain perception is modulated in the dorsal spine by the dispute at the entrance of the nonnociceptive Aβ nerves that transmit superficial cutaneous, mechanical, and electrical information, and the nociceptive Aδ and C nerves that carry painful information. The Aβ nerves activated by the thermal stimulation of the capacitive resistive currents of the radiofrequency reduce the transmission of painful information and, consequently, intolerance to pain decreases.[9,10]

Despite the effectiveness of CRMRF in other musculoskeletal pathologies having been demonstrated,[5–7] there is scarce evidence of its benefits when applied as a pain and treatment management for CPPS.[10,11]

The aim of this study is therefore to evaluate the efficacy of CRMRF therapy versus sham CRMRF treatment, both combined with pain education and physiotherapeutic techniques, with respect to pain reduction and QoL improvement in CPPS patients. The study also assesses side effects and treatment adherence.

2 | MATERIALS AND METHODS

This trial was made up of 81 consecutive adult patients with a CPPS diagnosis. It was conducted in Barcelona from March 2019 to April 2021. Inclusion criteria were to be aged 18 years or more, and to present one of the following for at least the previous 6 months: endometriosis, adenomyosis, myofascial syndrome, levator ani syndrome, bladder pain syndrome, inflammatory prostatitis, pudendal nerve syndrome, and nonspecific CPPS. Exclusion criteria were: (1) patients undergoing manual therapy, physical therapy, chiropractic massage, osteopathy, or any other conservative treatment throughout the study period; (2) subjects having recently undergone oncological processes, any treatment with chemotherapy/radiotherapy in the pelvic area, and surgery in the pelvic area in the previous 3 months; (3) individuals presenting pregnancy, chronic fatigue/fibromyalgia, severe psychological conditions, skin hypersensitivity, and neuromuscular diseases.

2.1 | Sample size

The grandaria mostral sample size calculation program was employed (version 7.12). To complete the estimation, 5% α values and 20% β values (power of 80%) were taken into account. Basing the study on data and published literature,[12] and assuming a common three standard deviation (SD) and a difference ≥ 2 in the visual analogue scale (VAS), it was concluded that 40 patients were needed for each arm of the study, assuming a maximum of 10% follow-up losses/dropouts. A 1:1 ratio was generated for a randomized allocation sequence.

The allocation sequence was concealed from the researcher (A. C.-M) enrolling and assessing participants in sequentially numbered, opaque, sealed, and stapled envelopes. To prevent subversion of the allocation sequence, the computerized number of their medical records and date of birth of the participant was written on the envelope. Corresponding envelopes were opened only after the enrolled participants completed all baseline assessments and it was time to allocate the intervention.

The study was approved by the Vall d'Hebron Hospital ethics committee (PR(RAP)361/2018) and all participants signed an informed consent form before commencement of treatment.

2.2 | Randomization

Study participants were identified by the computerized number of their medical records and categorized

sequentially according to order of recruitment. To randomly create the participant groups, the CRMRF engineer team entered the randomized sequence corresponding to each study number to designate the control group (CG) and the intervention group (IG) participants.

Four indications were taken into account to blind patients, physiotherapists, and the principal investigator to the assigned study group: (1) the screen visible to the CRMF team showed no parameter that could indicate whether or not the equipment emitted an electrical signal; (2) a 2% intensity parameter was established for all participants to prevent the IG from receiving any thermal effect; (3) to avoid any sensation, physiotherapists applied the CRMRF by manipulating it with the handle, never with the electrode (training was given before study commencement); (4) randomization and allocation sequences were concealed at all times from the patients, principal investigator, and health professionals until statistical analysis was performed on completion of the intervention.

2.3 | Intervention

As part of the initial assessment each subject underwent a physical examination and their complete medical record reviewed. Treatment consisted of 10 CRMRF sessions (INDIBA, 350 VA, and 100 W at 448 kHz, INDIBA S.A.) performed once a week. Both groups were given pain education consisting of pain and central sensitization concepts, gate control theory, and notions on the neurotransmitters that can influence (increase/decrease) pain.[13] All patients received CRMRF using a 35 mm resistive electrode combined with simultaneous physiotherapeutic techniques and pain education based on the location of the pain (Table 1), however CG participants received deactivated CRMRF.

Furthermore, as recommended by the literature for CPPS treatment, depending on the patient's pain location, the physiotherapeutic techniques for each individualized session were exactly the same[14] (Table 1). They commenced with slow, smooth and increasingly direct

TABLE 1 Physiotherapeutic techniques and position of the patient during treatment sessions, depending on the pain location

	Anterior location (abdomen, pubis, groin, perineum, vagina, penis, and testicles)	**Posterior location (lumbar, sacrum, coccyx, buttocks, anus, and rectum)**
Position	Patient in supine position. CRMRF plate on lower back	Patient in the prone position. CRMRF plate on abdomen
Techniques	Abdominal area	Lumbosacral area
	Lift techniques of the peritoneum	Relaxation of the quadratus lumbar
	Liberation of the urachus	Relaxation of the paravertebral muscles
	Groin area	Gluteal area
	Stretching the inguinal ligament	Decompression of the pudendal nerve in the greater sciatic foramen
	Myotensive techniques of the internal obturator	Stretching of the sacrociatic ligament
	Vulvar, perineal and vaginal area	Stretching of the sacrotuberous ligament
	Relaxation of the superficial fascia of the perineum	Release of the pudendal nerve in the ischiorectal fossa
	Stretching the prevesical ligament	Myotensive techniques of the pyramidal
	Uterine release techniques	Myotensive techniques of the external obturator
	Stretching of the round ligament	Anorectal area
	Stretching of the wide ligament	Sacral plexus release techniques
	Relaxation of the sacrorectogenitopubian laminae	Relaxation of the sacrorectogenitopubian laminae
	Release of the pudendal nerve in Alcock's canal	Stretching the Denonvilliers fascia
	Penis and testicular area	Prostate release techniques
	Relaxation of the superficial fascia of the perineum	
	Relaxation of the deep fascia of the perineum	
	Testicular drainage	
	If there is a scar, manual scar work is performed and the 35 mm resistive electrode is applied over it.	

movements that began distally and became more localized.[15]

To improve adherence to treatment and follow-up this information was emphasized to all patients. The team of physical therapists of this study were specifically trained to avoid bias originated by lack of standardization.

2.4 | Outcome measures

Following guidelines from the International Consultation on Incontinence (ICI) on assessing pain intensity, the VAS score was used[16] and a difference of at least two points was taken as the primary outcome measure. Additionally the SF-12 health survey (Spanish adaptation) was used to assess QoL as a secondary outcome measure. Participants completed one assessment at baseline and two additional ones at 5 and 10 weeks after the first session.

After each treatment session, adverse events were noted on the patient's record sheet. Adherence was also evaluated with a compliance form specifically designed for this study. The most common adverse reaction to CRMRF, as described in the equipment use manual, appears mainly at treatment commencement and consists of an increase in pain in the area lasting 2−3 days. This adverse reaction can be controlled with oral analgesics and local heat application. Very infrequently, the latter can cause dermal irritation requiring the application of topical treatments. In the case of any persistent dermal irritation the intervention ceased until symptoms completely disappeared, and this secondary effect was added to the patient's clinical record.

2.5 | Statistical methods

Statistical analyses were performed with SPSS 24.0 software. Data are reported as mean values and SD for quantitative variables, and with points and percentages for qualitative ones. Baseline characteristics and main outcomes were compared with a Student t test or Mann−Whitney U depending on normal distribution and χ^2 test.

Within-group comparisons at Week 5 and 10 were performed with Student's t test and χ^2 test. Efficacy was assessed by estimating the differences between the mean values of the outcome variables and their corresponding 95% confidence intervals (95% CI), as recommended by CONSORT.[17] The analysis was done per-protocol (PP) and by intention-to-treat (ITT). A $p < 0.05$ significance level was established.

3 | RESULTS

3.1 | Baseline characteristics

Of the 82 eligible participants 1 was excluded due to pregnancy. Figure 1 depicts the participant flow chart.

Eighty-one patients (men, $n = 26$) took part in the study. Mean age was 43.6 years (SD 12.9), and the mean duration of symptoms was 57.8 months (SD 63.4) ranging from 6 months to 25 years. Around half the patients presented myofascial syndrome (50.6%) and 44.4% had myofascial syndrome linked with other disorders. The majority were diagnosed with CPPS due to endometriosis (14.8%), bladder pain syndrome (14.8%), and prostatitis (11.1%).

The participants reported pain in the anterior part of the pelvis (46.9%), the posterior part of the pelvis (42%), and most of them located pain in the central part of their pelvis with no irradiation to the lateral part of the body (80.2%) at baseline.

The participants' demographic and clinical characteristics are shown in Table 2.

3.2 | Evaluation after 10 treatment sessions

A PP analysis was carried out in 70 patients who correcty completed the VAS assessment and the SF-12 survey. ITT analysis was also performed considering a total of 81 VAS scores and QoL surveys.

3.3 | Reduction in pain intensity

After 10 CRMRF treatment sessions, pain improved significantly (Table 3A). End PP evaluation showed a statistically significant reduction of 2.80 points (95% CI: 3.69−1.96) in the IG mean values, whereas the CG showed a mean reduction of 1.22 points (95% CI: 2.10−0.44) ($p = 0.013$). Figure 2A depicts the evolution of the VAS scores over time. The ITT analysis presented a statistically significant reduction of 2.74 (95% CI: 3.51−1.92) points in the IG versus 0.95 (95% CI: 1.7−0.33) points in the CG at treatment termination ($p = 0.002$). Furthermore, a statistically significant mean reduction of pain ($p = 0.020$) of 1.59 points (95% CI: 2.33−0.82) in the IG was observed at the fifth treatment session, compared to a mean decrease of 0.29 points (95% CI: −1.03 to −0.37) in the CG.

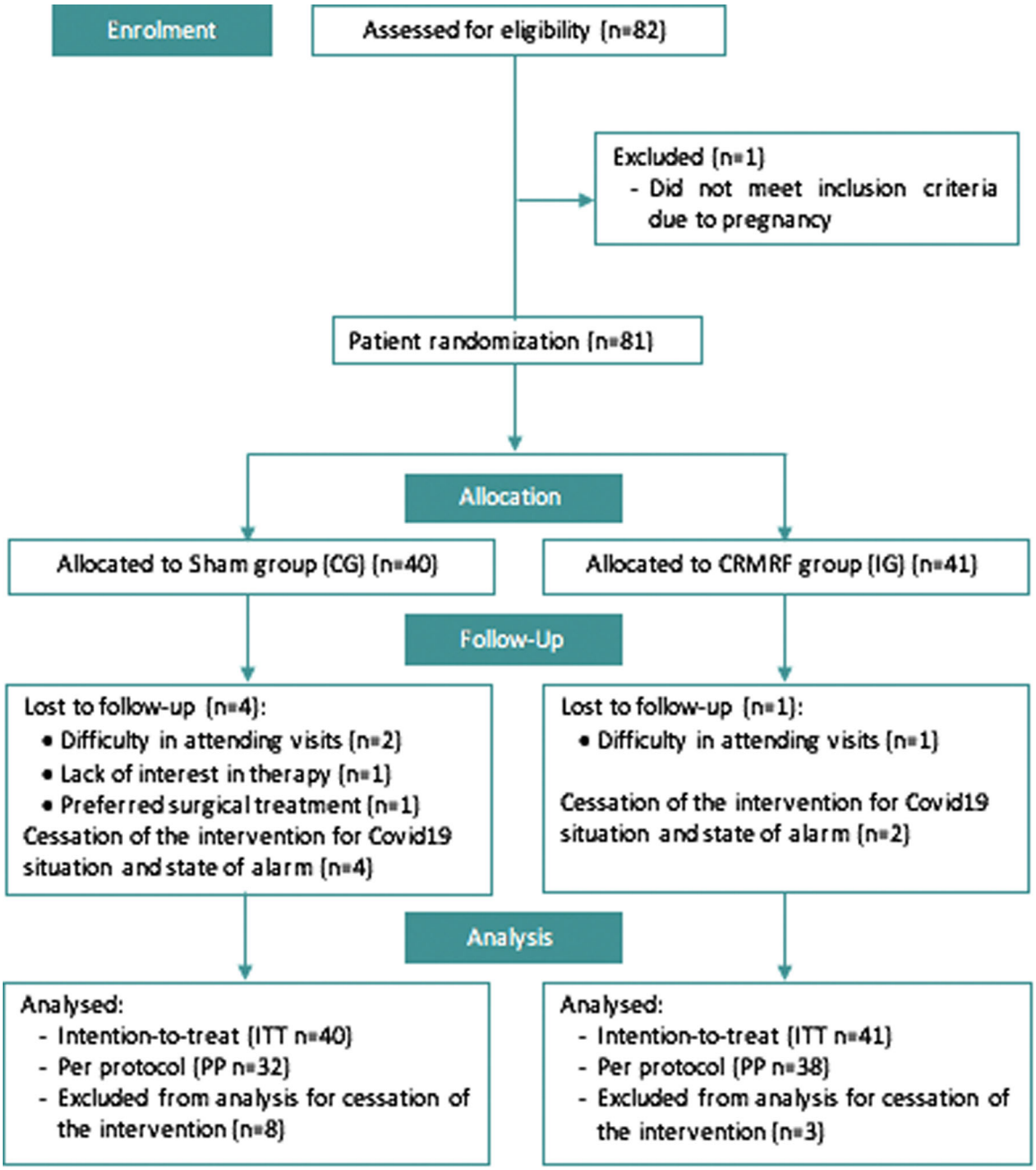

FIGURE 1 CONSORT participant flow diagram for randomized controlled trials. CG, control group; IG, intervention group; ITT, intention-to-treat; PP, per protocol

3.4 | Patients' assessments: QoL scores

There was no statistically significant difference between the SF-12 scores of each study group in PP analysis after treatment termination. Figure 2B shows the evolution of the values obtained through the SF-12 questionnaire over time. Even though the IG and CG achieved a mean increase in the physical and mental domains, suggestive of a minor impact on lower urinary tract dysfunction on the perceived QoL, these changes were nonstatistically significant.

The ITT analysis indicated a statistically significant difference ($p = 0.034$) in the physical SF-12 summary at the end of treatment of 4.70 (SD 6.40) points for the IG compared to 1.33 (SD 7.68) points for the CG. The mental SF-12 summary was unchanged between treatments and at termination (Table 3B).

In both analyses, a statistically significant improvement was noticed in the physical functioning domain ($p < 0.037$), where an increase in QoL > 5 points was observed in the IG compared to 0.99 points in the CG. An enhancement was noted in all the other domains of the

TABLE 2 Baseline demographic and clinical characteristics of CRMRF group and sham treatment groups

	IG $n = 41$	CG $n = 40$	Total $n = 81$
Gender (female), *n* (%)	28 (68.3)	27 (67.5)	55 (67.9)
Age, mean as years (SD)	43.8 (14.3)	43.3 (11.5)	43.6 (12.9)
Duration of symptoms, mean as years (SD)	5.6 (5.7)	4.1 (4.7)	4.8 (5.3)
Surgical interventions, *n* (%)			
Without previous surgery	11 (26.8)	8 (20.0)	19 (23.5)
Urological surgery	9 (22.0)	5 (12.5)	14 (17.3)
Gynecological surgery	9 (22.0)	17 (42.5)	26 (32.1)
Other surgeries non uro-gynecological	12 (29.2)	10 (25.0)	22 (27.1)
Physical exercise (1−2 times a week or less), *n* (%)	32 (78.0)	27 (67.5)	59 (72.8)
Current drug treatment,[a] *n* (%)			
No treatment or not relevant	12 (29.3)	12 (30.0)	24 (29.6)
Analgesics/anti-inflammatories	16 (39.0)	15 (37.5)	31 (38.3)
Antidepressants/anxiolytics	7 (17.1)	9 (22.5)	16 (19.8)
Antiepileptic drugs	6 (14.6)	4 (10.0)	10 (12.3)
Chronic pelvic pain syndrome etiology, *n* (%)			
Inflammatory prostatitis	4 (9.8)	6 (15.0)	10 (12.3)
Endometriosis/adenomyosis	6 (14.6)	6 (15.0)	12 (14.8)
Bladder pain syndrome	5 (12.2)	1 (2.5)	6 (7.4)
Pudendal nerve syndrome	3 (7.3)	1 (2.5)	4 (4.9)
Nonspecific CPPS	4 (9.8)	2 (5.0)	6 (7.4)
Presence of myofascial syndrome, *n* (%)	18 (43.9)	25 (62.5)	43 (53.1)
Presence of myofascial syndrome associated with other disorders, *n* (%)	22 (53.7)	14 (35.0)	36 (44.4)

Note: Values expressed as mean (SD) and number of patients (percentage).

Abbreviations: CG, control group; IG, intervention group; *n*, number of patients; SD, standard deviation.

[a]The list of analgesics/anti-inflammatories/phytotherapy includes: paracetamol, ibuprofen, dexketoprofen, tramadol, tebetane, and permixon. The list of antidepressants includes: amitriptyline, duloxetine, fluoxetine, and lorazepam. The list of antiepileptic drugs includes: pregabalin, gabapentin, and clonazepam.

questionnaire at the end of the treatment, these differences, however, were not statistically significant (Table 3C).

3.5 | Side effects and adherence

No serious adverse events were reported. Overall adherence to treatment was 86.4% (70/81 patients), with 92.7% (38/41) adherence in the IG versus 80.0% (32/40) in the CG, the difference was not statistically significant ($p = 0.096$).

4 | DISCUSSION

A number of publications have already reported the efficacy of physiotherapy as a treatment for CPPS.[18,19] The present study adds to these findings by objectively evaluating CRMRF procedure together with manual physical therapy and educational techniques, in comparison to CRMRF sham treatment also with manual physical therapy and identical educational techniques, regarding efficacy in reducing pain and improving QoL in CPPS patients. This is the first time that such a technique has been assessed by means of a randomized

TABLE 3 Parameter changes after 10 weeks of CRMRF and sham treatments

	ITT			PP		
	IG ($n = 41$)	CG ($n = 40$)	p Value	IG ($n = 38$)	CG ($n = 32$)	p Value
A. Visual analogic scale						
Baseline	5.93 (2.46)	4.87 (2.37)		5.95 (2.49)	4.83 (2.42)	
10 session	3.19 (2.78)	3.92 (2.76)		3.15 (2.78)	3.61 (2.79)	
Difference from baseline	−2.74 (−3.51; –1.92)	−0.95 (−1.70; −0.33)	**0.002**	−2.80 (−3.69; −1.96)	−1.22 (−2.10; −0.44)	**0.013**
B. SF-12 questionnaire						
Physical summary						
Baseline	40.34 (11.10)	42.30 (11.18)		39.79 (10.76)	42.31 (12.22)	
10 session	45.04 (10.77)	43.63 (10.92)		44.90 (10.62)	43.65 (11.17)	
Difference from baseline	4.70 (2.82; 6.59)	1.33 (−1.11; 3.64)	**0.034**	5.11 (3.15; 7.15)	1.90 (−0.55; 4.56)	0.057
Mental summary						
Baseline	39.06 (9.08)	40.30 (9.39)		38.75 (9.17)	40.84 (9.13)	
10 session	42.38 (7.92)	44.03 (8.13)		42.14 (7.89)	45.12 (7.85)	
Difference from baseline	3.32 (0.54; 6.37)	3.73 (1.53; 6.14)	0.831	3.39 (0.43; 6.52)	4.28 (1.47; 6.99)	0.678
C. SF-12 Domains (difference from baseline)						
General health (GH)	2.43 (0.38; 4.57)	2.49 (1.04; 4.04)	0.964	2.40 (0.01; 4.81)	2.59 (0.67; 4.49)	0.899
Physical functioning (PF)	5.23 (2.71; 7.76)	0.99 (−1.69; 3.87)	**0.037**	5.64 (2.95; 8.77)	0.99 (−1.81; 3.84)	**0.028**
Role physical (RP)	5.70 (2.52; 9.02)	2.44 (−0.25; 5.05)	0.131	6.15 (2.87; 9.92)	3.05 (−0.24; 6.43)	0.207
Role emotional (RE)	4.16 (0.0; 7.92)	3.74 (0.86; 6.75)	0.869	4.21 (0.13; 8.48)	4.52 (1.15; 8.30)	0.916
Bodily pain (BP)	4.92 (2.72; 7.15)	2.69 (0.19; 5.23)	0.213	5.31 (3.05; 8.03)	3.99 (0.99; 7.10)	0.500
Mental health (MH)	4.39 (1.85; 6.98)	3.46 (0.69; 5.97)	0.623	4.61 (1.98; 7.41)	3.42 (0.30; 6.04)	0.560
Vitality (VT)	2.54 (0.00; 5.08)	2.20 (0.17; 4.21)	0.837	2.74 (0.19; 5.41)	3.00 (0.96; 5.22)	0.884
Social function (SF)	4.74 (2.01; 7.47)	2.43 (−0.20; 5.10)	0.234	5.11 (2.49; 8.09)	3.59 (−0.49; 6.55)	0.471

Note: Values expressed as mean (standard deviation) and mean (95% confidence interval). p value calculated by Student's t test for independent samples. Values in bold indicate statistically significant p values.

Abbreviations: CG, control group; IG, intervention group; ITT, intention-to-treat analysis; n, number of patients; PP, protocol analysis.

controlled trial (RCT). Our results show that the response to CRMRF therapy (IG) was superior to that reported for the CRMRF sham one (CG) in the treatment of myofascial syndrome, as suggested in our hypothesis, and in a similar manner to other painful disorders.[5,20–22]

To the best of the authors' knowledge, only two previous studies have investigated the efficacy of CRMRF in reducing pelvic perineal pain. One of them was the RCT by Bretelle et al.[11] conducted in postpartum women with perineal tears or episiotomy. They concluded that applying CRMRF to the perineum on the first day following delivery reduced discomfort when walking and decreased paracetamol consumption. The second was a quasi-experimental study by Fernández-Cuadros et al.[10] conducted in 37 patients with CPPS and/or dyspareunia. They observed a reduction in pain and an improvement in muscle strength after eight sessions of manometric biofeedback followed by CRMRF.

Whilst our study participants differ from those in the trial by Bretelle et al.[11] they are similar to those in the study by Fernández-Cuadros et al.[10] The latter, however, was a quasi-experimental/before-after study which

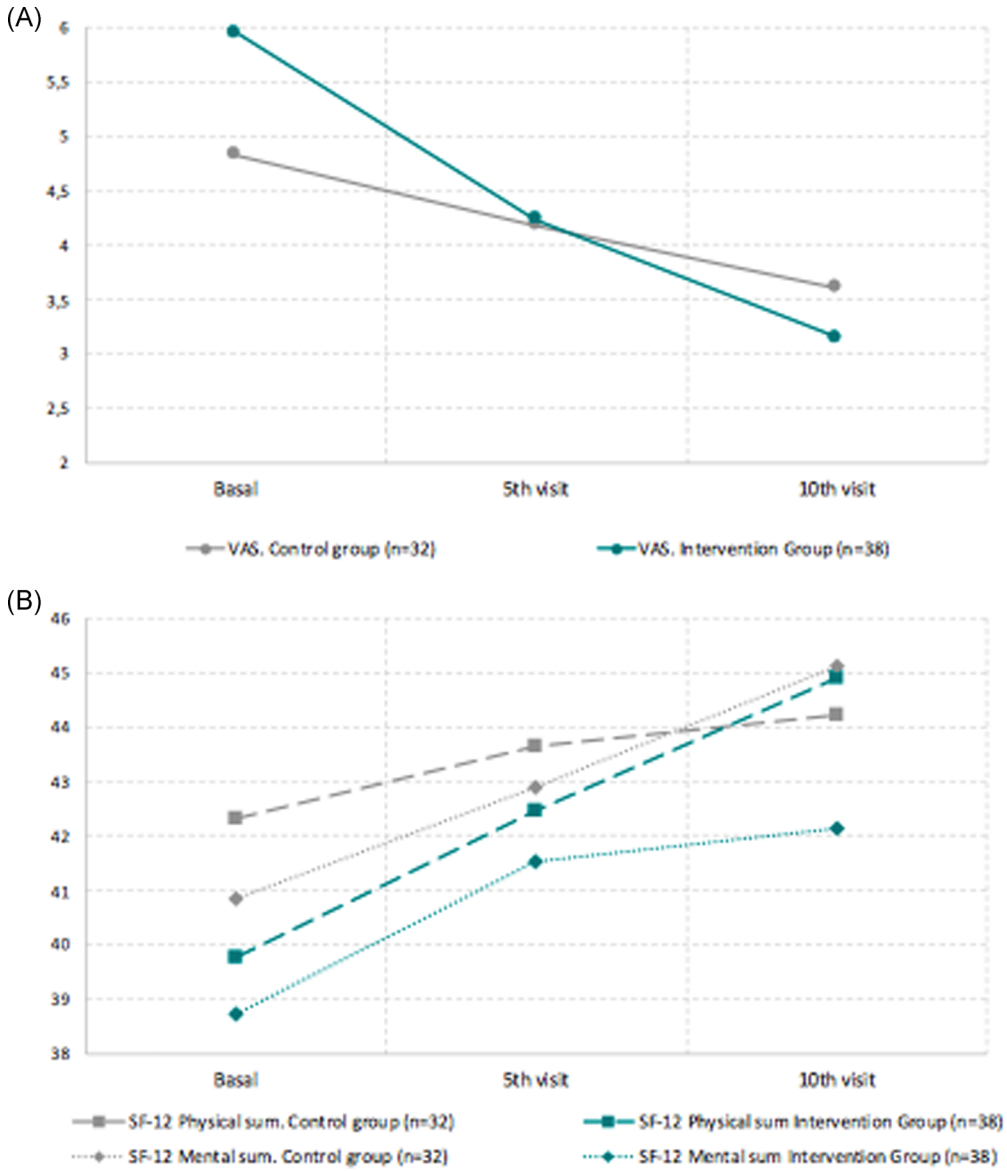

FIGURE 2 Intensity of pain (VAS) (A) and quality of life related to health (SF-12 survey) (B) values at baseline, 5 weeks, and end of treatment (Week 10). Per protocol analysis. VAS, visual analogue scale

employed neither randomization nor blinding procedures leading to a possibly higher risk of participant selection. Moreover, two therapies were simultaneously applied. In contrast, the present study was designed as a RCT with a greater number of patients and thus provides stronger and better evidence than previously published research.

Regarding demographic variables, the mean age (44.7 years), sex, and time of evolution are the usual ones in patients with this clinical condition.[13,19,23,24]

With respect to our findings, a decrease of almost 3 points in the VAS was observed in the IG, concurring with the CRMRF study by Fernández-Cuadros,[10] and those by Diego et al.[21] and Kumaran & Watson.[5] They also reported an analgesic effect after eight sessions of CRMRF treatment, although in other musculoskeletal disorders. The statistically significant decrease by almost 3 points observed in the VAS score in the IG group was similar to the findings of other authors using CRMRF in various musculoskeletal disorders. Moreover, it was higher than the minimal clinical important difference described in other chronic pelvic pain populations.[25]

Despite a lower scoring (1 point in the VAS), our CG also showed a reduction in pain intensity which could have been due to the myofascial therapy applied in parallel with sham CRMRF therapy as described by FitzGerald et al.[24]

On treatment termination, favorable changes in QoL were reported according to the SF-12v2 questionnaire in the two treatment groups. Such improvements in both

the physical and mental computations and the 8 dimensions concurred with studies evaluating myofascial therapy as a therapeutic option.[24] With the exception of the study conducted by Kumaran & Watson.[5] for the treatment of chronic osteoarthritis, QoL has not been previously evaluated in studies with CRMRF in the pelvic floor.

A high rate of treatment adherence to treatment was attained (86.4%) aligned to figures reported in similar investigations.[18,24]

Before radiofrequency, deep thermotherapy, ultrasound, and diathermy were frequently used in clinical practice. Such therapies improve hemoglobin saturation and increase deep tissue temperature more than superficial thermotherapy. Currently, however, they are infrequently used to treat CPPS due to the risk of periosteal inflammation. Moreover, most diathermy devices with frequencies of 8–14 MHz produce excessive heat during treatment which can cause skin burns if a polus or surface-cooling system is not employed.[7–8]

CRMRF at 448 kHz has been recently developed as a form of deep thermotherapy to deliver radiofrequency energy which passes between active and inactive electrodes. It does not require a polus or surface-cooling system because the 448 kHz it utilizes is lower than that used in conservative diathermy. As a result, this treatment does not cause excessive heat generation between the skin and the electrode, making it safer to use than other diathermy devices.[5–8,20]

4.1 | Limitations

The study was blinded and sham-controlled, nevertheless, the perception of being treated/observed in the two groups must be taken into account. The mere fact of being observed may have induced improvement in symptoms for some participants (positive Hawthorne effect). In contrast, some subjects may have over-expressed symptoms (negative Hawthorne effect). As it occurred in both groups, the effect should not influence the values of the difference in outcomes between the IG and the CG. Even so, it may have led to an overestimation of the response to therapy in both groups, and it is possible that the positive results obtained in the trial may not be extrapolated to routine clinical practice.

To avoid selection bias, we compared baseline pathologies and found that there was homogeneity for both groups, except for the characteristic gynecological surgery. Despite the fact that, according to the CONSORT statement, it could be understood that any difference might be the result of chance and not a selection bias, we consider we have properly covered this issue as a limitation. On the other hand, we did not take into account this variation between both groups because, in most cases, such interventions had been performed several years before commencement of the pain. Moreover, they did not appear to be either the etiology or trigger of the pain experienced by the patient.

Our study was designed only to identify a difference between the two participating groups at short and medium term. Longer follow-up studies are warranted. Moreover, a cost-effectiveness analysis was not performed. This approach would be of interest to compare CRMRF therapy with other existing techniques in terms of resource use and effectiveness. Further research determining the most cost-effective way of applying the CRMRF technique is called for. In a similar manner, more prospective studies are required to evaluate response to CRMRF procedure in a larger population, including assessment of optimal frequency and duration of treatment, and establishing stimulation parameters for the greatest efficacy and cost-effectiveness.

5 | CONCLUSIONS

To the best of our knowledge, this is the first randomized clinical trial to evaluate the efficacy of the CRMRF technique compared to the same sham technique and demonstrate its superiority in decreasing pain intensity in CPPS patients. In addition, the differences observed in the other patient-reported outcomes, such as health-related QoL, denote statistically significant advances.

Both technique applications ameliorated symptoms and to a large extent QoL even though the perception of improvement differed between the two groups. These results, and the ease of use of CRMRF, should encourage more frequent prescription of this procedure.

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CONFLICTS OF INTEREST

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ETHICS STATEMENT

This study has been evaluated and approved by the Research Ethics Committee of the Vall d'Hebron University Hospital (Comité de Ética de Investigación con Medicamentos y comisión de proyectos de investigación del Hospital Universitari Vall d'Hebron) (PR(RAP)361/2018). The development of the project is based on following and respecting the bioethical principles of beneficence, nonmaleficence, autonomy, justice, dignity, and privacy, the Declaration of Human Rights, the Belmont Report, and the International Declaration on Bioethics and Human Rights of UNESCO. It is also grounded in the statements of the World Medical Association of Helsinki, the Deontological Code of the Association of Medical Colleges of Spain, and the Deontological Code of Physiotherapists of Catalonia and Spain. All patients will be informed verbally and via an information sheet and will be required to sign the informed consent. Participation in the study may be interrupted by the patient at any time if desired, and without negative consequences for the individual. All data collected will be confidential, respecting the Spanish data protection law (LOPD Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales). Likewise, the privacy of each participant will be respected at all times. Only the principal investigator, the physiotherapists who perform the interventions, and the statistical analyst will have access to the final data set. This clinical trial will be registered at clinicaltrials.gov clinicaltrials.gov and data will be updated systematically, as well as any changes to the protocol. The aim is to publish the results in the form of a doctoral thesis by the principal investigator.

AUTHOR CONTRIBUTIONS

This study has been fortunate to receive input and advice from a wide range of experts in their respective fields. Andrea Carralero-Martínez and Inés Ramírez-García were responsible for the study concept and initial design. Both of them wrote the first draft of the manuscript and were involved in its interpretation and critical review. The first and second authors (Andrea Carralero-Martínez and Miguel Angel Muñoz) were responsible for the study design and statistical analysis. Andrea Carralero-Martínez was responsible for gathering data and test reporting. Stèphanie Kauffmann and Laia Blanco-Ratto reviewed the scientific literature. All authors approved the final version of the manuscript.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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