Efficacy of capacitive resistive monopolar radiofrequency in the physiotherapeutic treatment of chronic pelvic pain syndrome: study protocol for a Randomized Controlled Trial

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Study protocol

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Abstract

Background

Chronic Pelvic Pain Syndrome (CPPS) is a multifactorial disorder that affects 5.7–26.6% of women and 2.2–9.7% of men, characterized by a hypersensitivity of the central and peripheral nervous system affecting bladder and genital function. People with CPPS have much higher rates of psychological disorders (anxiety, depression, and catastrophizing) that increase the severity of chronic pain and worsen quality of life. Myofascial therapy, manual therapy, and treatment of trigger points are proven therapeutic options for this syndrome. The aim of this study is to evaluate the efficacy of capacitive resistive monopolar radiofrequency (CRMRF) at 448 KHz as an adjunct treatment to the other physiotherapeutic techniques for reducing pain and improving the quality of life of patients with CPPS.

Methods

This triple-blind (1:1) randomized controlled trial will include 80 women and men with CPPS. Participants will be randomized into CRMRF activated group or CRMRF deactivated group, together with physiotherapeutic techniques and pain education. The groups will receive treatment for 10 consecutive weeks. Pain intensity (with the VAS), quality of life (with the SF-12), kinesiophobia (with the TSK-11) and catastrophism (with the PCS) will be evaluated at the beginning, at the sixth and the tenth session.

Discussion

The results of this study will make it possible to prove that CRMRF benefits the treatment of patients with CPPS together with physiotherapeutic techniques and pain education. These results could offer another conservative treatment option for these patients.

Trial registration:

ClinicalTrials.gov Identifier: NCT03797911. Registered 8 January 2019, https://clinicaltrials.gov/ct2/show/NCT03797911

Background

Chronic Pelvic Pain Syndrome (CPPS) is defined as “pain of non-oncological cause, intermittent or constant, in the lower part of the abdomen or pelvis, in both men and women, lasting at least 6 months, and with negative consequences that can be cognitive, behavioral, sexual and emotional" [1–2]. It is a multifactorial disorder serious enough to cause urinary and genital functional disability and with a high prevalence (5.7–26.6% of women, and 2.2–9.7% of men) [3–8].

People with CPPS have much higher rates of psychological distress. The prevalence of anxiety ranges between 39–73% compared to the general population (12%), as the prevalence of depression is 26–52% compared to 5–10% of the general population [9–13]. These conditions, along with catastrophizing, are associated with an increased severity of chronic pain and reduction of quality of life [4, 14–18].

In addition, people with CPPS tend to have central and peripheral nervous system hypersensitivity, with dysfunctional pain modulation that tends to aggravate pain [19–24].

In physical therapy consultations, there are a variety of therapeutic options with sufficient evidence to guide physical therapy for patients with CPPS [25]. The most widely used is myofascial therapy, although this group of patients should be treated from a multidisciplinary approach along with other therapies such as psychology, medication or surgery when other treatments have failed [26, 27]. One of these options in clinical practice is capacitive resistive monopolar radiofrequency (CRMRF) at 448 KHz, which consists of a non-invasive strategy that increases the temperature of deep organs or tissues through the action of radiofrequency electrical currents with the aim of reducing pain and inflammation and increasing tissue repair [28–35]. There are few recent studies that evaluate its clinical efficacy despite the fact that its practice has been common for the last 20 years [36]. Current studies report promising results in terms of pain reduction and improved function in musculoskeletal pathologies (such as low back pain) [37] and tendinopathies (such as plantar fasciitis) [38–40].

In spite of its demonstrated efficacy in other musculoskeletal pathologies, there is currently insufficient scientific evidence regarding its role in the management of CPPS.

Methods

The aim

The study hypothesizes that the application of CRMRF associated with physiotherapy techniques and health education provides benefits in reducing pain compared to physiotherapy and health education techniques alone in the management of patients with CPPS.

The specific aims are to evaluate the efficacy of the CRMRF according to the intensity of pain, quality of life, kinesiophobia and catastrophism of the patients participating in the study. In addition, sociodemographic and clinical data, adherence to treatment and possible adverse effects during treatment will be recorded in both groups.

Study design

This manuscript describes a research protocol for a triple blind, randomized controlled clinical trial. Participants will be equal (1:1) randomly allocated into activate capacitive resistive monopolar radiofrequency group (intervention group, IG) and deactivate capacitive resistive monopolar radiofrequency (control group, CG). Both groups will receive pain education and physiotherapeutic

techniques (myofascial therapy, trigger point therapy, and/or manual therapy). Participants, the investigators performing the intervention and the statistical analyses will be blinded.

An analysis of the results will be carried out at six and ten weeks of treatment.

Study locations

This trial will take place at RAPbarcelona pelvic floor specialized physiotherapy center in Barcelona.

Study population

Patients who consult in the center for a first visit or who are derived from other health professionals who know the protocol of this study, will be invited to participate in this study.

To be eligible, participants must meet the following criteria. Inclusion criteria: Being of legal age, suffering from CPPS for 6 months or more (etiologies will include: Myofascial Syndrome, Endometriosis, Adenomyosis, Abacterial Prostatitis, Interstitial Cystitis, Levator Ani Syndrome, Pudendal Nerve Syndrome, Nonspecific CPPS) and accepting to participate in the study granting signed informed consent. Exclusion criteria: undergoing other conservative treatments during the study, having undergone treatment with chemotherapy or radiotherapy in the pelvic area, having recently undergone an oncological process, being pregnant, having undergone surgery in the pelvic area in the last 3 months, presenting fibromyalgia or chronic fatigue, suffering serious psyche disorders, presenting hypersensitivity in the skin that may be in contact with the treatment, and suffering neuromuscular diseases.

Investigations

Patients who agree to participate in the study will be given an appointment by telephone and will receive CRMRF therapy for 30 minutes once a week (except for the first session, which will last 45–60 minutes to deliver the patient information and sign the informed consent, to resolve doubts about the study, about the questionnaires and, finally, to explain the theory of pain and health education).

At baseline, participants will undergo an initial assessment where data on age, medical history, surgical history and clinical data will be collected. According to criteria used in previous similar studies [41, 42] a palpation of the abdominal, lumbosacral, and perineal region will be performed, followed by internal palpation using the index finger at the vaginal and/or anal level to palpate the pelvic floor muscles, tissue connective and internal organs, and localize pain. The Visual Analogic Scale (VAS) to measure the intensity of pain, the health questionnaire Short Form 12 (SF-12) to assess their quality of life, the Tampa Scale for Kinesiophobia (TSK-11) to assess kinesiophobia, and the Pain Catastrophizing Scale (PCS) to assess catastrophism will be evaluated at first visit. The same tests will be re-evaluated at 6 and 10 sessions. Also, in each session, treatment adherence and possible adverse effects of the therapy will be identified and recorded in a database designed for the project.

A total of ten treatment physiotherapy sessions will be held on a weekly basis (Table 1).

Both groups will follow the same protocol that will consist of applying the CRMRF (INDIBA Activ CT8→) at 2% to induce an electrical and athermic effect, along with pain education and physiotherapeutic techniques [43, 44] according to the location of the pain (Table 2) that will be applied at the same time as the CRMRF. Participants will be placed comfortably in a supine or prone position (depending on the area to be treated) with a pillow under their heads, without pants or underwear. The plate will be placed on the abdomen or lower back depending on the patient's position on the stretcher, and the 32 mm resistive electrode will be used to apply the CRMRF to the painful area.

Table 1
Treatment sessions

	Intervention group (IG)	Control group (CG)
SESSION 1	Delivery of the information sheet and signing of the informed consent. Collection and recording of baseline data (age, sociodemographic data, clinical data, and medical and surgical history). Self-completion of tests (VAS, SF-12, TSK-11 and PCS).	
	Application of physiotherapeutic techniques with activated CRMRF. Explanation of the theory of pain and health education.	Application of physiotherapeutic techniques with deactivated CRMRF. Explanation of the theory of pain and health education.
SESSION 2–5	Session protocol: • Registration of possible discomfort or adverse effects perceived by the patient. • Application of physiotherapeutic techniques with activated CRMRF. • Pain education clarifications	Session protocol: • Registration of possible discomfort or adverse effects perceived by the patient. • Application of physiotherapeutic techniques with deactivated CRMRF. • Pain education clarifications
SESSION 6	Collection of VAS, SF-12, TSK-11 and PCS tests. Session protocol (as described in session 2–5)	
SESSION 7–9	Session protocol (as described in session 2–5)	
SESSION 10	Session protocol (as described in session 2–5) Assessment of VAS, SF-12, TSK-11, PCS tests, evolution of the pathology and referral (if required).	

Participants in the IG will receive the treatment with the activated CRMRF (emitting electrical signal) and the participants in the CG will receive the same treatment with the deactivated CRMRF (without emitting electrical signal).

This CRMRF equipment is designed to perform the conventional treatment (IG) and a placebo treatment (CG) without being visible to either the therapist or the participant. The team produces an automatic

randomization for each participant according to the order of study assignment.

Pain education will consist of a basic theory about gate control [45], concepts of pain and central sensitization, and a basic explanation of the neurotransmitters that influence the increase or decrease in pain [46–48].

The physiotherapeutic techniques that will be performed in each session will always be the same in all individualized treatment sessions for each patient that will be assigned according to the location of the pain (Table 2). These will be those recommended by the literature for the treatment of CPPS, which will consist of myofascial induction techniques, trigger point therapy, and manual therapy with the aim of improving the elasticity of the musculature and fascial tissue and improving blood flow. These techniques will be performed with smooth and slow movements, and always from more indirect to more direct, and from more distal to more local [49].

Table 2
Physiotherapeutic techniques and position of the patient during treatment sessions, depending on the location of the pain

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

As this is a study with multiple tests and interventions, several physical therapists will be needed to be able to carry it out. For this reason, to avoid errors due to lack of standardization, there will be a training period in the application of the therapy and data collection for all the physiotherapists who will participate in the study.

Outcome measures

Participants will complete three study assessments: baseline, 6 and 10 weeks after first session.

Primary outcome:

- Intensity of pain: According to the VAS score, evaluated in the first, sixth and tenth sessions of the study. This quantitative and subjective variable consists of marking the degree of intensity of pain in a straight horizontal line of fixed length of 10cm. The ends are defined as the extreme limits of the parameter to be measured orientated from the left (worst) to the right (best) [50, 51].

Secondary outcomes:

- Quality of life related to health: Measured with the SF-12 Quality of Life health questionnaire. Is a generic questionnaire that we will use the Spanish adaptation done by Alonso et al [52, 53] of the SF-12 Health Survey [54, 55]. The SF-12 is a reduced version of the SF-36 Health Questionnaire designed for cases in which this is too long. The SF-12 is answered in an average of ≤ 2 min and the SF-36 needs between 5 and 10 min. It consists of 12 items from the 8 dimensions of the SF-36 (physical function, social function, physical role, emotional role, mental health, vitality, body pain and general health status). Higher score means better quality of life.
- Kinesiophobia: Fear of movement will be measured by Tampa Scale for Kinesiophobia (TSK-11). This questionnaire created by Miller et al [56] quantifies the intensity of kinesiophobia suffered by the patient, and we will use the reduced version and adaptation to Spanish by Gómez-Pérez et al [57]. It consists of 11 statements that the patient must answer using a Likert-type scale from 1 (totally disagree) to 4 (totally agree). Higher score means higher degree of kinesiophobia.
- Catastrophizing: Measured with the Pain Catastrophizing Scale (PCS) [58]. This 13-item questionnaire assesses the patient's catastrophic thoughts using a five-point Likert scale. It consists of three subscales (rumination, magnification, hopelessness). Higher score means higher degree of catastrophizing. The Spanish adaptation validated by García Campayo et al [59] will be used.
- Sociodemographic variables, pathological history and clinical history: Assessed in the first session of the treatment, collected through a standardized clinical history.
- Adverse effects: Recorded in each of the treatment sessions through the patient references about his status and evolution.
- Adherence to treatment: Assessed in each of the treatment sessions, collected through a compliance from designed for the project.

Schedule

Table 3
The different schedule phases are shown in italics.

	Recruitment	Session 1	Sessions 2–5	Session 6	Sessions 7–9	Session 10
Recruitment:						
Selection screening	X					
Informed consent	X					
Allocation	X					
Interventions:						
Intervention CG (deactivated CRMRF		X	X	X	X	X
Intervention IG (activated CRMRF)		X	X	X	X	X
Evaluations:						
Descriptive variables		X				
Clinical variables		X				
VAS		X		X		X
SF-12		X		X		X
TSK-11		X		X		X
PCS		X		X		X
Compliance form		X	X	X	X	X
Recording of adverse effects		X	X	X	X	X

Sample size

To estimate the sample size, we use the sample size calculator of the “GRANMO” program. This version 7.12 of April 2012 can be obtained at the following link on the website https://www.imim.es/ofertadeserveis/software-public/granmo/.

For this estimate, alpha values of 5% and beta of 20% (power of 80%) were taken into account. Based on data published in the literature [60] and applying a common standard deviation of 3 and a difference equal to or greater than 2 in the VAS, 40 patients are needed in each arm of the study, assuming a maximum percentage of follow-up losses/dropouts of 10%.

Selection of the sample

The selection of the sample will be done by sampling of consecutive cases, from RAPbarcelona clinic in Barcelona. Health professionals from other institutions will be contacted to increase referrals to the center, and an advertising campaign will be carried out on social networks. In physiotherapists appointments, patients with CPPS will be referred to the principal investigator. The protocol will be clearly explained to each of the interested patients who meet all the selection criteria, and he will be asked to sign the informed consent if accept participation. After the signature the patient will be allocated to one of the two study groups.

Random allocation of groups

Once the participants are included in the study, they will be identified from the number of the computerized Medical Record, and they will be ordered sequentially and consecutively from 1 to 80 according to the order of recruitment. To assign interventions, CRMRF team engineers will enter into the software the randomized sequence corresponding to each number from 1 to 80 to designate the CG and IG participants. In order to keep the assigned study group hidden from the patient, the physiotherapist and the main researcher, the following four indications will be taken into account: 1) No parameter will appear at any time on the visible screen of the CRMRF team that can reflect if the machine performs any activity. 2) The current intensity parameter will be 2% in all participants, to prevent the intervention group patients from perceiving any thermal effect. 3) The physiotherapists will perform the application of the CRMRF by manipulating the equipment with the handle and never with the electrode to avoid any sensation. They will be trained before starting the study. 4) The sequence of randomization and allocation will be kept hidden at all times for all patients, professionals and for the main researcher, until the statistical analysis once the entire intervention is finished.

Collection, management and data analysis

The data will be collected in a specific database coded for this study, which will only be available to the main researcher. The database and statistical analysis will be performed with IBM SPSS Statistics 24.0 software.

First, a descriptive analysis of the characteristics of the patients included in both study groups, as well as the outcome variables will be carried out. To do this, absolute and relative frequencies (percentages) will be estimated for qualitative variables, and mean or median and standard deviation or range, respectively, depending on the normality of the distribution, for quantitative variables. Afterwards, the comparative analysis of the two treatment groups will be carried out using the Chi-square test for qualitative variables, and with the Student's t test for quantitative variables. Additionally, different associations between diverse variables will be analyzed. To check for the efficacy of the study treatments, intention to treat (ITT) and by protocol (PP) analysis will be performed.

The comparison of results will be done by estimating the differences in a timely manner and with their corresponding 95% confidence intervals (95% CI).

Additionally, the adjusted differences will be calculated, following the indications of the CONSORT document [61]. In all cases, the level of statistical significance established will be the usual (5%); therefore, statistically significant differences will be considered when p values are less than 0.05.

Discussion

The results of this study will make it possible to prove that CRMRF benefits the treatment of patients with CPPS together with physiotherapeutic techniques and pain education. These results could offer another conservative treatment option for these patients.

Trial Status

This is the first version of the protocol (January 28, 2021). Recruitment began in April 2019 and the intervention has had to stop due to the coronavirus crisis. For this reason, the completion is expected for next April.

Declarations

Ethics approval and consent to participate

This protocol 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 on 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 sign the informed consent. Participation in the study may be interrupted by the patient at any time, if desired, and without negative consequences for him.

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 of the participants will be respected at all times. Only the principal investigator, the physiotherapists who performed the interventions and the statistical analyst will have access to the final data set.

The aim is to publish the results in the form of doctoral thesis of the principal investigator.

Consent for publish

Not applicable

Availability of data and materials

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Not funding.

Authors' contributions

ACM and IRG were responsible for the study conception and design. MAMP collaboratively conceptualized the study objectives and methodology and provided a critical revision of the manuscript. RPA, SK and LBR helped conceptualize and design the study. All authors read and approved the final manuscript.

The authors declared that INDIBA SAU (ES) has no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Abbreviations

CG: Control Group

CPPS: Chronic Pelvic Pain Syndrome

CRMRF: Capacitive Resistive Monopolar Radiofrequency

IG: Intervention group

PCS: Pain Catastrophizing Scale

SF-12: Health Questionnaire Short Form 12

TSK-11: Tampa Scale for Kinesiophobia

VAS: Visual Analogic Scale

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