STUDY PROTOCOL, STATISTICAL ANALYSIS PLAN AND INFORMED CONSENT FORM

Official Title

Effectiveness of Capacitive-Resistive Radiofrequency and Lumbopelvic-Pelvic Floor Exercise, Alone or Combined, for Chronic Low Back Pain in Premenopausal Women With Pelvic Floor Dysfunction: a Three-Arm Randomised Controlled Trial

Item	Details
ClinicalTrials.gov identifier	[NCT number pending]
Document date	[DATE: 18 October 2026]
Protocol version	Approved by the Biomedical Research Ethics Committee of Universidad CEU Cardenal Herrera, report CEEI25/763 (19 January 2026)
Sponsor	Universidad Cardenal Herrera-CEU, Elche, Spain
Principal investigator	Cristina Orts Ruiz, PhD
Study site	Centre Osmose Saint-Loup, Marseille, France

Contents

- Part A. Study Protocol (including Appendix A1, exercise programme)
- Part B. Statistical Analysis Plan
- Part C. Participant Information Sheet and Informed Consent Form

PART A. STUDY PROTOCOL

1. Administrative information

Item	Details
Official title	Effectiveness of Capacitive-Resistive Radiofrequency and Lumbopelvic-Pelvic Floor Exercise, Alone or Combined, for Chronic Low Back Pain in Premenopausal Women With Pelvic Floor Dysfunction: a Three-Arm Randomised Controlled Trial
Title approved by the ethics committee (Spanish)	Efectividad de la aplicación de radiofrecuencia y el ejercicio físico terapéutico de la musculatura lumbar y de suelo pélvico para el tratamiento del dolor lumbar crónico en mujeres con disfunción del suelo pélvico. Ensayo clínico aleatorizado.
Trial registration	ClinicalTrials.gov [NCT number pending]
Protocol version	Version approved by the Biomedical Research Ethics Committee of Universidad CEU Cardenal Herrera (report CEEI25/763, meeting of 19 January 2026), as reported in the protocol manuscript submitted to BMJ Open.
Sponsor	Universidad Cardenal Herrera-CEU, CEU Universities, Elche, Spain
Principal investigator	Cristina Orts Ruiz, PhD - Department of Physiotherapy, Faculty of Health Sciences, Universidad Cardenal Herrera-CEU, Elche, Spain
Investigators	Marie Anne Riquier (Centre Osmose Saint-Loup; Universidad Cardenal Herrera-CEU); Cristina Salar-Andreu; Sergio Montero-Navarro; Jesús Sánchez-Más; Olivia Tournier
Study site	Centre Osmose Saint-Loup, 220 Boulevard de Saint-Loup, 13010 Marseille, France
Funding	No specific grant from any funding agency. Capenergy Medical (Barcelona, Spain) loans a Capenergy C500 Urogyne device as in-kind support and has no role in study design, data collection, analysis, interpretation or the decision to publish.
Competing interests	None declared.

2. Background and rationale

Non-specific chronic low back pain (CLBP) is pain between the lower costal margin and the sacral region that persists for more than 12 weeks and cannot be attributed to a specific pathology. It is a leading global cause of disability, is more prevalent in women than in men, and generates substantial healthcare and productivity costs.

Contemporary models of CLBP emphasise the lumbopelvic “core”, a coordinated system that includes the lumbar multifidus, transversus abdominis, diaphragm and pelvic floor muscles (PFM). The PFM support the pelvic organs and contribute to intra-abdominal pressure and lumbopelvic stiffness. CLBP and pelvic floor dysfunction frequently co-occur in women: in one cross-sectional study of women with lumbopelvic pain, 95.3% had some form of pelvic floor dysfunction.

Exercise therapy is first-line conservative treatment for CLBP, and programmes combining core stabilisation with PFM training reduce pain and disability. A systematic review and meta-analysis concluded that PFM-strengthening exercise reduces low back pain intensity. Adherence to exercise, however, is often limited.

Capacitive-resistive electric transfer (radiofrequency, RF) delivers high-frequency electromagnetic energy that produces endogenous deep heating, vasodilation and reduced nociceptive sensitivity. Lumbar RF has improved short-term pain, disability and range of motion in CLBP, and intravaginal RF has reduced stress urinary incontinence symptoms. No randomised trial has evaluated pelvic-floor RF for lumbar pain, nor compared RF, supervised lumbopelvic-PFM exercise and their combination in women with CLBP and pelvic floor dysfunction.

3. Objectives

General objective. To evaluate the effectiveness of radiofrequency and therapeutic exercise applied to the lumbar and pelvic regions, alone or combined, on symptoms in premenopausal women with non-specific CLBP and pelvic floor dysfunction.

Primary objective. To compare lumbar pain intensity (0-10 VAS) among the three intervention groups 1 week after the end of the assigned intervention.

Secondary objectives.

- To compare pain quality, lumbar disability, pelvic floor symptoms, urinary incontinence, PFM function and lumbar mobility among groups at 1 week, 1 month and 3 months after the intervention.
- To determine the association between pelvic floor dysfunction symptoms and the perception of chronic low back pain after radiofrequency and/or exercise.
- To describe the safety of the interventions (adverse events).

4. Trial design

Single-centre, three-arm, parallel-group, assessor-blinded randomised controlled trial with a 1:1:1 allocation ratio. The trial compares three active conservative strategies: (i) capacitive-resistive RF applied to the lumbar region and pelvic floor; (ii) a 12-week supervised therapeutic exercise programme targeting the lumbopelvic core and PFM; and (iii) the combination of RF and exercise. There is no untreated control arm. The protocol follows the SPIRIT 2025 statement.

5. Study setting

Centre Osmose Saint-Loup, Marseille, France (SIRET 918 455 288 00012). The clinic has a private physiotherapy room suitable for RF and PFM assessment and an exercise room for group sessions. A written site authorisation is in place. Recruitment and intervention are planned to start in October 2026.

6. Eligibility criteria

Inclusion criteria. Women are eligible if they meet all of the following:

- Age 18 years or older.
- Non-specific low back pain located between T12 and the iliac crest, with or without referred pain to the lower limb.
- Pain duration of more than 12 consecutive weeks.
- Pain intensity of 3/10 or higher on a 0-10 visual analogue scale (VAS) at screening.
- Pelvic floor dysfunction, defined as a score above 0 on either the Pelvic Floor Distress Inventory short form (PFDI-20) or the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-SF).

Exclusion criteria. Women are excluded if they have any of the following:

- Perimenopause or menopause.
- Chronic pain in regions other than the lumbar and pelvic areas.
- Current pregnancy or lactation.
- Physiotherapist-supervised PFM training in the previous 12 months.
- Pharmacological treatment for any pelvic floor disorder.
- RF applied to the PFM in the previous 12 months.
- Inability to understand study information (cognitive impairment).
- Cardiac, metabolic or autoimmune disease.
- Peripheral or central neurological disorder.
- Previous abdominal, lumbar or pelvic surgery.

- Skin disease or open wounds in the treatment area.
- Active urinary tract or vaginal infection.

The restriction to premenopausal women is intended to reduce hormonal heterogeneity in PFM function and symptom reporting.

7. Interventions

7.1 Radiofrequency

RF is delivered with a capacitive-resistive device designed for urogynaecological and musculoskeletal applications (Capenergy C500 Urogyne; capacitive probe and return plate). Two applications are given in the same visit:

- **Lumbar application.** The participant lies prone. A pulsed emission (840 kHz, 30 V) is applied dynamically (rotational and translational movements) over active myofascial trigger points of quadratus lumborum, multifidus and iliocostalis. The active plate is placed on the lumbar region and the return plate on the abdomen. Duration: 20 minutes.
- **Pelvic application (simultaneous).** A covered, lubricated vaginal electrode is used with the return plate on the lumbar region. The operator performs a complete vaginal sweep in clock-face quadrants (0-3, 3-6, 6-9, 9-12) for 20 minutes, titrating intensity to a high but non-burning thermal sensation. Kilojoules delivered and temperature achieved are recorded after each session.

Nine sessions are given at 7-day intervals. Tolerance is monitored continuously and intensity is reduced if the participant reports pain or discomfort. The procedure is stopped if a clinically important adverse reaction occurs (burn, marked irritation or persistent pain), and appropriate care is provided.

7.2 Therapeutic exercise

The programme lasts 12 weeks, with three supervised 30-minute sessions per week (36 sessions), delivered in groups of at most five participants by physiotherapists experienced in therapeutic exercise and pelvic floor rehabilitation. Week 1 begins with an individual session covering anatomy, breathing and technique, with digital checking of PFM contraction. Sessions progress from isolated PFM and transversus abdominis activation to combined core, gluteal and synergistic work in static and dynamic positions, including resisted expiration and brief apnoea to facilitate lumbopelvic co-activation. Load increases after weeks 4 and 8 (anti-gravity positions, movement and external resistance with kettlebell or ball). Stretching and relaxation are included for their analgesic effect. Typical dosage is three sets of 10 repetitions with a slow count of five between sets, adjusted to the baseline PERFECT profile. Attendance is recorded on a session log. The session-by-session programme is given in Appendix A1.

7.3 Combined intervention

Participants allocated to the combined arm receive the RF protocol and the exercise programme concurrently, delivered by the same clinical team and using the same dose, progression and recording forms as the single-modality arms.

7.4 Concomitant care

No trial-specific restrictions are placed on usual analgesic use; concomitant treatments are recorded. Participants are asked not to start a new supervised PFM or RF programme outside the trial.

8. Outcomes

Assessments are performed at baseline (before randomisation), 1 week after the assigned intervention ends, and 1 and 3 months after the end of intervention.

Primary outcome. Lumbar pain intensity on a 10-cm VAS 1 week after the last session of the assigned intervention (after week 9 in the RF-only arm and after week 12 in the exercise and combined arms). This end-of-treatment time point was chosen because the two programmes have different durations.

Secondary outcomes (all at baseline, 1 week, 1 month and 3 months after intervention):

- Pain intensity (VAS) at 1 and 3 months.

- Pain quality: McGill Pain Questionnaire (MPQ).
- Lumbar disability: Oswestry Disability Index (ODI; 0-100%).
- Pelvic floor symptom burden: PFDI-20 total and subscales (UDI-6, POPDI-6, CRADI-8).
- Urinary incontinence: ICIQ-SF.
- PFM function: after voiding and 3 minutes of seated rest, participants are examined in lithotomy. Function is graded with the PERFECT scheme (power, endurance, repetitions, fast contractions, every contraction timed) and the modified Oxford scale (0-5). Intravaginal pressure is measured with an air-filled probe connected to a Phenix Liberty manometer (Electronic Concept Lignon Innovation, Montpellier, France): resting tone and mean of three maximal 10-second holds.
- Lumbar mobility and pain location: modified Schober test (flexion); passive lumbar extension test; bilateral side-bending fingertip-to-thigh distance (difference below 10 cm classified as restricted); palpatory mapping of pain between T12 and the iliac crests.
- Kinesiophobia: Tampa Scale for Kinesiophobia (TSK-17; 17 items, range 17-68; higher scores indicate greater fear of movement).
- Pain catastrophising: Pain Catastrophizing Scale (PCS; 13 items, range 0-52; subscales rumination, magnification and helplessness).
- Adverse events, recorded throughout the intervention and follow-up.

Sociodemographic, anthropometric, lifestyle and gynaecological-obstetric data are collected at baseline with an ad hoc questionnaire (age, body mass index, educational level, occupation, smoking, physical activity, parity, obstetric history, menstrual status and current analgesic use).

9. Participant timeline (SPIRIT schedule)

Item	t0 Screening / baseline	t1 Intervention	t2 1 week post	t3 1 month post	t4 3 months post
Eligibility screen	X				
Written informed consent	X				
Ad hoc sociodemographic and clinical questionnaire	X				
Randomisation (1:1:1)	X				
Radiofrequency (9 weekly sessions)		X			
Therapeutic exercise (3 sessions/week × 12 weeks)		X			
Attendance log / RF dose record		X			
Pain intensity (VAS) - primary outcome	X		X	X	X
McGill Pain Questionnaire	X		X	X	X
Oswestry Disability Index	X		X	X	X
PFDI-20	X		X	X	X
ICIQ-SF	X		X	X	X
PFM function (PERFECT, modified Oxford)	X		X	X	X
Intravaginal pressure (manometry)	X		X	X	X
Lumbar mobility and pain mapping	X		X	X	X
TSK-17 (kinesiophobia)	X		X	X	X

Item	t0 Screening / baseline	t1 Intervention	t2 1 week post	t3 1 month post	t4 3 months post
Pain Catastrophizing Scale	X		X	X	X
Adverse events		X	X	X	X

t2-t4 are anchored to the end of each participant's assigned programme (RF 9 weeks; exercise and combined 12 weeks) rather than to a common calendar week. In the combined arm both interventions are delivered during the same calendar period.

10. Sample size

The sample size was calculated in G*Power from a three-arm randomised trial of capacitive-resistive transfer in non-specific CLBP that showed significant short-term effects on pain and function. A two-sided α of 0.05, power of 95% and a large between-group effect (Cohen's f = 0.50) for a one-way analysis of variance on the primary outcome were specified. Allowing for 15% attrition yielded 60 participants (20 per arm). A change of 2 points on a 0-10 pain scale, or 10 points on the ODI, is commonly regarded as clinically important in CLBP; the trial is not separately powered for responder analyses.

11. Recruitment

Participants are recruited from women attending Centre Osmose Saint-Loup with CLBP and through public advertisements on Instagram, Facebook, TikTok and LinkedIn. An investigator records a short information video describing the trial aims, eligibility and procedures. The same investigator conducts the first contact, provides a French-language participant information sheet and obtains written informed consent before any study-specific procedure.

12. Allocation

After baseline assessment, participants are randomly assigned 1:1:1 to RF, exercise or combined RF plus exercise. The allocation sequence is generated by an independent investigator using SAS 9.4 (SAS Institute, Cary, NC, USA). Treatment codes are stored in a restricted database accessible only to the clinician responsible for delivering the assigned intervention.

13. Blinding

Outcome assessors and the trial statistician remain unaware of group assignment; the statistician analyses coded data. Participants and treating physiotherapists cannot be blinded because of the nature of the interventions; this limitation will be acknowledged when interpreting self-reported outcomes.

14. Data collection and management

Standardised paper forms (PERFECT/manometry sheet, lumbar mobility sheet, RF dose sheet, exercise attendance log) and validated questionnaires are used. Data are entered into a coded electronic file stored on the institutional OneDrive of Fundación Universitaria San Pablo CEU (FUSP-CEU), with access restricted to named investigators by individual password. Direct identifiers are replaced by a study code and paper source documents are kept under lock at the study site. Processing complies with Regulation (EU) 2016/679 (GDPR) and Spanish Organic Law 3/2018. Data that could link a participant to study variables are kept for the duration of the project (estimated 2 years from ethics approval) and then destroyed.

15. Safety monitoring and harms

RF intensity is titrated to tolerance at every session. Expected RF effects are transient erythema or oedema, which typically resolve within 1-2 days. Exercise is physiotherapist-supervised to limit technique-related injury. Adverse events are recorded, assessed for relatedness and seriousness, managed clinically at the study site and reported to the ethics committee according to institutional rules. No interim efficacy analysis or data monitoring committee is planned. There is no separate trial

insurance beyond standard professional and clinical coverage at the participating centre; participants who experience a trial-related injury receive appropriate clinical care.

16. Ethics and consent

The protocol, participant information sheet and informed consent form were approved by the Biomedical Research Ethics Committee of Universidad CEU Cardenal Herrera (report CEEI25/763; meeting 19 January 2026; favourable opinion; validity 1 year). The trial is conducted in accordance with the Declaration of Helsinki, ICH Good Clinical Practice principles, the GDPR, Spanish Organic Law 3/2018 and applicable French site regulations. Written informed consent is obtained before any study-specific procedure (Part C). Participation is voluntary and consent may be withdrawn at any time without effect on usual clinical care; if a participant withdraws, no new data are collected. Any substantial amendment (sample size, eligibility, outcomes, sites or investigators) will be submitted to the ethics committee before implementation and updated in the trial registry. The data controller is FUSP-CEU; the Data Protection Officer can be contacted at C/ Tutor 35, 28008 Madrid, Spain, or dpd@ceu.es.

17. Dissemination

There are no publication restrictions. Results will be submitted to a peer-reviewed journal regardless of the direction of the findings and posted on the trial registry. A plain-language summary will be offered to participants. Authorship will follow ICMJE criteria.

Appendix A1. Session-by-session therapeutic exercise programme

Unless otherwise stated, each exercise is performed in 3 sets of 10 repetitions, with rest between sets while counting slowly to five. Session 1 is an individual session; subsequent sessions are delivered in groups of up to five participants.

Sessions	Exercises
Session 1 (individual)	Individual treatment-room session: anatomical concepts, breathing and exercise technique, with digital testing of correct PFM contraction. The number of sustained and fast contractions and apnoea time are prescribed according to the baseline assessment.
Sessions 2, 4, 6, 8, 10	1) Supine, knees bent, heels supported and ankles dorsiflexed: self-elongation with transversus abdominis and PFM activation during resisted expiration. 2) Same, adding a glute bridge. 3) Same bridge with unilateral hip flexion and knee extension; repeat with the other leg. 4) After two full breaths, self-elongation with transversus and PFM activation held in apnoea for 10 s. 5) Same with glute bridge. 6) Same with bridge, hip flexion and single-leg raise; repeat with the other leg. 7) Supine, hips and knees at 90° with a ball between the knees: hip and knee flexion-extension with adductor activation, exhaling on lowering (10 repetitions). 8) Kneeling plank: 30 s on / 30 s rest × 5. 9) Kneeling side plank: 30 s on / 30 s rest × 5 per side. 10) Active stretching.
Sessions 3, 5, 7, 9, 11	1) Pelvic awareness and proprioception on a fitball (circles in both directions and figure-of-eight). 2) Sitting on the fitball: sustained and fast PFM contractions. 3) Sitting on the fitball, heels down and toes up: after two full breaths, self-elongation with transversus and PFM activation held in apnoea for 10 s. 4) Same with single-leg raise; repeat with the other leg. 5) Supine, hips, knees and ankles at 90°: resisted expiration with self-elongation and transversus/PFM activation while alternating straight-arm flexion (10 per side). 6) Quadruped: contralateral arm and leg raise during resisted expiration (10 per side). 7) Quadruped pelvic tilt with transversus activation and PFM awareness (10 repetitions). 8) Quadruped hypopressive exercise (apnoea after two full breaths, 10-s hold) with arm flexion and leg extension, both sides (downward-dog position). 9) Dynamic stretching.

Sessions	Exercises
Sessions 12, 14, 16, 18, 20, 22, 24	1) Supine glute bridge with resisted expiration, transversus/PFM activation and unilateral leg extension, both sides (10). 2) Supine bridge lifting a kettlebell on the pelvis while exhaling and contracting abdomen and PFM (10). 3) Supine, hips and knees at 90° squeezing a ball: feet to ceiling and lowered without touching the floor (10). 4) Running on the spot with alternate knee lifts, with core activation and PFM awareness (3 × 20 s). 5) Balance and motor control with kettlebell on a stable, then unstable, base (10). 6) Isometric squat with kettlebell, 3-s hold, activating transversus and PFM (10). 7) Deep squat with kettlebell (10). 8) Alternating forward lunges holding a kettlebell (10 per leg). 9) Burpees with transversus and PFM activation (10). 10) Dynamic stretching.
Sessions 13, 15, 17, 19, 21, 23	1) Supine glute bridge with normal breathing and automatic core/PFM activation (10). 2) Same with alternate straight-leg raise (10). 3) Supine, legs at 90° with a ball: hip and knee flexion-extension with adductor activation and normal breathing (10). 4) Forearm front plank, 90 s; rest 30 s. 5) Straight-arm front plank, 90 s; rest 30 s. 6) Side plank on extended arm, 90 s per side; rest 30 s. 7) Front plank with alternating opposite arm and leg raise (5 per side). 8) Straight-arm plank bringing knee to same-side elbow, alternating (10). 9) Crunch with normal breathing (10). 10) Lateral crunch with two kettlebells or weights reaching to each heel (10). 11) Seated oblique rotation with kettlebell, trunk reclined and feet off the floor (10 per side). 12) Dynamic stretching.

Translated from Annex 11 of the ethics-approved protocol. The approved annex details sessions 1-24.

PART B. STATISTICAL ANALYSIS PLAN

1. Purpose and responsibilities

This plan describes the pre-specified analyses for the trial. Analyses will be performed in IBM SPSS Statistics version 29 by the trial statistician (Jesús Sánchez-Más), who will analyse coded data and remain blinded to group allocation and to data collection.

2. Analysis populations

- **Intention-to-treat (ITT) population.** All randomised participants, analysed in the group to which they were allocated. This is the primary analysis population.
- **Complete-case population.** Participants with observed outcome data at the relevant time point; used for sensitivity analyses.

3. Outcomes and time points

The primary outcome is lumbar pain intensity (0-10 cm VAS) 1 week after the end of the assigned intervention. Secondary outcomes are VAS at 1 and 3 months, McGill Pain Questionnaire, ODI, PFDI-20 (total and subscales), ICIQ-SF, PFM function (PERFECT scheme, modified Oxford scale, intravaginal manometry), lumbar mobility, palpatory pain mapping, TSK-17 and PCS. Outcomes are measured at baseline (t0) and at 1 week (t2), 1 month (t3) and 3 months (t4) after the end of the assigned intervention.

4. General principles

- All tests are two-sided with a significance level of 0.05.
- Baseline characteristics are summarised by group: mean and standard deviation or median and interquartile range for continuous variables, and counts and percentages for categorical variables.
- Distributional assumptions are inspected with the Kolmogorov-Smirnov test and graphical methods (histograms and Q-Q plots).

5. Primary analysis

The principal inferential model is a repeated-measures analysis of variance with group (RF, exercise, combined) as the between-subject factor, time (t0, t2, t3, t4) as the within-subject factor and a group × time interaction. If group imbalance or missing data require it, a linear mixed model with the same fixed effects will be used instead. The primary comparison is the between-group difference in VAS at t2. Between-group comparisons at each time point use one-way ANOVA or, when assumptions are not met, the Kruskal-Wallis test.

6. Secondary analyses

- Each continuous secondary outcome is analysed with the same repeated-measures model (group, time, group × time).
- Between-group comparisons at each time point: ANOVA or Kruskal-Wallis test for continuous variables; χ^2 or Fisher's exact test for categorical variables.
- Within-group change from baseline: paired t test or Wilcoxon signed-rank test for continuous variables; McNemar or Bowker symmetry test for categorical variables.
- Associations between pelvic floor dysfunction symptoms (PFDI-20, ICIQ-SF) and lumbar pain perception after the interventions are examined with correlation analyses appropriate to the data distribution.

7. Missing data

The extent and pattern of missing outcome data will be examined. Multiple imputation will be used if the missingness mechanism is compatible with it (missing at random), with complete-case analyses as sensitivity checks.

8. Sensitivity analyses

- **Common calendar time.** VAS will also be compared among groups 13 weeks after randomisation, when all participants have completed their assigned programme. This addresses the fact that the RF-only arm reaches the end of treatment 3 weeks earlier than the other arms.
- **Complete-case analysis** of the primary and secondary outcomes.

9. Interim analyses

No interim efficacy analysis is planned.

10. Safety analysis

Adverse events will be tabulated descriptively by group, relatedness and seriousness.

11. Sample size

See Part A, section 10: 60 participants (20 per arm), based on a one-way ANOVA with Cohen's f = 0.50, two-sided $\alpha = 0.05$, power 95% and 15% attrition.

PART C. PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

> *English translation of the participant information sheet and informed consent form approved by the Biomedical Research Ethics Committee of Universidad CEU Cardenal Herrera (CEEI25/763; original in Spanish). Participants receive a French translation of the approved text. Personal identification numbers have been redacted for public posting.*

PARTICIPANT INFORMATION SHEET

Study title: Effectiveness of radiofrequency and therapeutic physical exercise of the lumbar and pelvic floor muscles for the treatment of chronic low back pain in women with pelvic floor dysfunction. Randomised clinical trial.

Principal investigator: Cristina Orts Ruiz - Universidad CEU Cardenal Herrera

Introduction

We are writing to inform you about a research study in which you are invited to take part.

Our intention is that you receive correct and sufficient information so that you can decide whether or not to take part in this study. Please take the time you need to read this information sheet carefully and discuss it with anyone you wish. Ask the study staff to explain any word or information that you do not clearly understand, as well as any question you may have.

If you decide to take part, we will ask you to sign the attached informed consent document. We will give you an original copy of this signed and dated document to keep, and the original will be filed with the rest of the study documentation.

The study has been approved by the Research Ethics Committee of Universidad CEU Cardenal Herrera, Valencia. It has been designed and will be conducted in accordance with the recommendations of the Declaration of Helsinki and the Standards of Good Clinical Practice.

Your participation in this study is voluntary and you may decide NOT to take part. If you decide to take part, you may change your decision and withdraw your consent at any time, without this affecting your relationship with your physiotherapist.

You may also be withdrawn from the study if the sponsor or the investigators consider it appropriate, for safety or other reasons. In any case, you will receive an adequate explanation of the reason for your withdrawal.

Why is this study being carried out?

Chronic low back pain affects a large proportion of women and has a considerable impact on their quality of life. Pelvic floor dysfunction has recently been linked to low back pain. When the pelvic floor is dysfunctional, it can alter stability and the distribution of forces in the body, which can modify lumbar stability and cause pain in the lower back.

The aim of the study is to evaluate the effectiveness of pelvic floor treatment based on physical exercise and radiofrequency as a complementary treatment to conventional treatment in women with chronic low back pain. These are non-invasive, painless treatments that have been very effective for pelvic floor dysfunction but have not yet been tested in patients with chronic low back pain.

How will the study be carried out?

A personalised treatment will be delivered by physiotherapists with extensive experience in pelvic floor care. Participants will be randomly assigned to one of the 3 treatment groups of the study: radiofrequency to the pelvic floor and lumbar region (RF, Group 1), exercises for the pelvic floor and lumbar region (Exercise, Group 2), or combined treatment (RF + exercise, Group 3).

The intervention will take place at Centre Osmose Saint-Loup, 220 Boulevard de Saint-Loup, 13010 Marseille, France.

The clinical trial will begin in June 2026. Radiofrequency is an electrotherapy-based treatment. A porcelain electrode specifically designed for the treatment of urogynaecological dysfunctions, covered with a latex probe cover, is introduced into the vagina to increase tissue temperature. This produces a

localised sensation of heat in the treated area, always kept as intense but non-burning heat. Radiofrequency will also be applied to the lumbar muscles. Radiofrequency treatment will consist of 9 sessions of 20 minutes, with an interval of 7 days between sessions. The physical exercise will consist of a lumbopelvic exercise programme, including pelvic floor activation, supervised by a physiotherapist three times a week, for 30 minutes, over 12 weeks.

Who can take part?

Adult women with pain located between T12 and the iliac crest, with or without pain referred to the lower limb, present for more than 12 weeks (chronic), with an intensity of 3/10 on the VAS scale, and with pelvic dysfunction determined by the PFDI-20 and ICIQ-SF questionnaires, with a score above 0 on one of these questionnaires.

You will not be able to take part if any of the following apply: menopause or perimenopause; chronic pain in areas other than the lumbar and pelvic regions; pregnancy; breastfeeding at the time of the study; physiotherapist-supervised pelvic floor muscle exercises in the last 12 months; pharmacological treatment for any pelvic dysfunction; inability to understand the information provided (cognitive impairment); cardiac, metabolic or autoimmune diseases; peripheral or central neurological disorders; previous surgery in the abdominal-lumbar or pelvic region; skin conditions or wounds in the treatment area; active urinary tract and/or vaginal infection.

What does my participation involve?

If you agree to take part, we will ask you to:

- Sign the informed consent. All information collected will be treated confidentially and used only for scientific purposes, protecting your identity at all times. For this, your express written consent is required.
- Complete a questionnaire to collect sociodemographic data (age, weight, occupation, education) and data related to lumbopelvic pain, using standard questionnaires validated for this type of study, and then attend a first clinical examination to assess pelvic floor muscle strength.
- Be randomly assigned to one of the three intervention groups.
- Attend the same clinical examination again 1 week after finishing treatment, and 1 month and 3 months after finishing treatment.

What risks or discomforts may I experience?

These are conservative, non-invasive and painless treatments.

Non-ablative radiofrequency works by selectively and gradually increasing tissue temperature. In this study the temperature will not exceed 41 °C, which almost completely reduces its possible adverse effects, which could be small areas of redness or swelling typical of skin warming. Although these effects are not associated with such low temperatures, if they occurred they would disappear within 1 or 2 days.

Physical exercise will be supervised by a professional, ensuring each exercise is performed correctly and thus reducing potential injury or pain due to incorrect practice. On the contrary, physical exercise is recommended for both physical and mental health.

What are the benefits of the study?

Participants will receive a complete, non-invasive and painless treatment which, according to previous studies in other groups with similar symptoms, is expected to have a positive effect on pelvic function and low back pain, and therefore on quality of life. The results will allow the effectiveness of safe, non-invasive and low-cost treatments to be compared, providing data of great clinical value for the development of conservative therapy programmes for chronic low back pain.

What treatment options do I have if I do not take part?

Women who decide not to take part will receive advice from the investigating physiotherapists on alternative conservative treatments, not linked to the study, that may be beneficial for them.

How are my rights protected?

The study will be conducted in compliance with all applicable ethical and legal standards.

Confidentiality. The investigators undertake to treat your personal data confidentially, in accordance with the applicable data-protection legislation (Spanish Organic Law 3/2018 on the Protection of Personal Data and Guarantee of Digital Rights, and Regulation (EU) 2016/679). The data collected for the study will be identified by a code that does not include information that could identify you, and only the investigators will be able to link these data to you and to your clinical record. Your identity will therefore not be disclosed to anyone, except in a medical emergency or where required by law.

Access to your identified personal information will be restricted to the investigators, health authorities, the Research Ethics Committee and personnel authorised by the sponsor (study monitors, auditors) when they need to verify study data and procedures, always maintaining confidentiality in accordance with current legislation.

Questionnaires containing personal data will be kept under lock at all times and only the investigators will have access to them. Data will be recorded anonymously in a research file under the responsibility of the investigators and processed on networked computers accessible only with a personal password.

In accordance with data-protection legislation, you may exercise your rights of access, rectification, objection and cancellation of your data by contacting your study physiotherapist. If you decide to withdraw your consent, no new data will be added to the database, but data already collected will be used.

Coded data may be transferred to third parties, but will never contain information that could directly identify you, such as your name, initials or clinical record number. Any such transfer will be for the same purposes as this study or for scientific publications, always maintaining confidentiality. The data collected will never be used for any other purpose; all data will be destroyed and/or deleted once the results of the research have been published in scientific journals.

Whom can I contact if I have questions?

If you have any questions, please contact Cristina Orts Ruiz (Universidad CEU Cardenal Herrera) at cristina.orts@uchceu.es. She is responsible for this research and will answer any question related to the study.

Whatever your decision, the research team thanks you for your time and attention.

INFORMED CONSENT FORM FOR PARTICIPATION IN A RESEARCH PROJECT

Project title: Effectiveness of radiofrequency and therapeutic physical exercise of the lumbar and pelvic floor muscles for the treatment of chronic low back pain in women with pelvic floor dysfunction. Randomised clinical trial.

Principal investigator: Dr Cristina Orts Ruiz

I, Mr/Ms _____, with identity document no. _____, freely and voluntarily

STATE THAT:

1. I have read and understood the information sheet about the study.
2. I have had the opportunity to ask questions.
3. My questions have been answered satisfactorily.
4. I have received sufficient information about the study and the tests to be performed.
5. I understand that participation is voluntary and that I can leave the study whenever I wish, without having to give explanations and without this affecting my medical care.
6. In accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, repealing Directive 95/46/EC, I have been informed that my personal data, obtained by completing this form and resulting from my participation in the project, will be processed under the responsibility of FUNDACIÓN UNIVERSITARIA SAN PABLO CEU (FUSP-CEU) for the purpose of managing my participation in this research project. I have also been informed: (a) that profiling is planned in order to analyse or predict aspects relating to my health; (b) that the processing is based on the consent I have given; (c) that my personal data will be kept only for the duration of the project, estimated at 2 years, and then destroyed, and may not be kept without first being anonymised; in any case, they may not be transferred without my express consent, which I do not give by this document; (d) that I may contact the Data Protection Officer of FUSP-CEU in writing at C/ Tutor nº 35, 28008 Madrid, Spain, or at dpd@ceu.es; (e) that, in accordance with the rights granted to me by current data-protection regulations, I may lodge a complaint with the competent supervisory authority, and may exercise my rights of access, rectification, restriction of processing, erasure, portability and objection, and withdraw the consent given, by writing to the responsible investigator at the contact address given in this document.
7. I agree that my written consent and other data will be available to the clinical research project in which I am participating and to its responsible investigator, Dr Cristina Orts Ruiz, always respecting confidentiality and guaranteeing that my data will not be publicly available in a way that could identify me.
8. The data collected for this study will be included, together with those of other participants, in a personal database of Universidad CEU Cardenal Herrera, to which only the investigators approved for this project will have access, all of whom are bound by professional secrecy or a confidentiality agreement.

I sign this information and consent document voluntarily to express my wish to take part in this research study on the effectiveness of radiofrequency and therapeutic physical exercise of the lumbar and pelvic floor muscles for the treatment of chronic low back pain in women with pelvic floor dysfunction (randomised clinical trial), until I decide otherwise. By signing this consent I do not waive any of my rights. I will receive a copy of this document to keep and consult in the future.

I therefore give my agreement and consent for the study described to be carried out with the help of the necessary, duly qualified and specialised personnel.

_____
The participant - signature, name and surname
Valencia, on ____ of _____ 2026

AUTHORISATION BY A RELATIVE OR GUARDIAN

Given that Mr/Ms _____, with identity document no. _____, is unable to give free, voluntary and informed authorisation for the treatments described in this document,

Mr/Ms _____, with identity document no. _____, in the capacity of (husband, wife, son/daughter, sibling, legal guardian, relative, close friend, carer) _____, decides, within the available clinical options, to give free, voluntary and informed agreement to the technique described for the treatments set out in this document.

_____
Signature
_____, on ____ of _____ 20____

INVESTIGATOR

Dr Cristina Orts Ruiz, identity document no. [redacted] · cristina.orts@uchceu.es · Tel. +34 965 42 64 86, ext. 67403

As investigator of Universidad CEU Cardenal Herrera, Valencia, I declare that I have provided the study participant and/or authorised person with all the information necessary for the intervention described in this document, and that I have confirmed, immediately before applying the technique, that the participant does not present any of the contraindications listed above, and that I have taken all necessary precautions for the intervention to be carried out correctly.

_____
Investigator's signature
_____, on ____ of _____ 20____

REVOCATION OF INFORMED CONSENT

I, Mr/Ms _____, with identity document no. _____, revoke the consent given on ____ / ____ / _____ and do not wish to continue the treatment, which I consider finished as of this date.

_____
Signature
_____, on ____ of _____ 20____