STUDY PROTOCOL, STATISTICAL ANALYSIS PLAN AND INFORMED CONSENT FORM

Official Title

Effectiveness of Radiofrequency and Physical Exercise on Symptoms Associated With Primary Dysmenorrhea: a Randomised Clinical Trial

Item	Details
ClinicalTrials.gov identifier	[NCT number pending]
Document date	[DATE: 2 November 2026]
Protocol version	Approved by the Biomedical Research Ethics Committee of Universidad CEU Cardenal Herrera, report CEEI25/670 (7 April 2025)
Sponsor	Universidad Cardenal Herrera-CEU, Elche, Spain
Principal investigator	Cristina Orts Ruiz, PhD
Study site	NG Clínicas - Clínica Ginecológica Juana Lafaja Mazuecos, Elche, Spain

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 Radiofrequency and Physical Exercise on Symptoms Associated with Primary Dysmenorrhea: a Randomised Clinical Trial
Title approved by the ethics committee (Spanish)	Efectividad de la radiofrecuencia y el ejercicio físico en la sintomatología asociada a dismenorrea primaria. Ensayo clínico aleatorizado
Trial registration	ClinicalTrials.gov [NCT number pending]
Ethics approval	Favourable opinion of the Biomedical Research Ethics Committee of Universidad CEU Cardenal Herrera, report CEEI25/670 (meeting of 7 April 2025).
Sponsor	Universidad Cardenal Herrera-CEU, Elche, Spain
Principal investigator	Cristina Orts Ruiz, PhD - Universidad Cardenal Herrera-CEU
Investigators	Cristina Salar Andreu, PhD; Juana Lafaja Mazuecos, MD (gynaecologist); Jesús Sánchez-Más, PhD; Sergio Montero Navarro, PhD
Study site	NG Clínicas - Clínica Ginecológica Juana Lafaja Mazuecos, Calle Beethoven 20, bajo 3, 03203 Elche (Alicante), Spain

2. Background and rationale

Dysmenorrhea is pelvic and abdominal pain occurring during menstruation, sometimes beginning before it and radiating to the lower back and thighs. Primary dysmenorrhea is menstrual pain in the absence of pelvic pathology. It usually begins 6-12 months after menarche, peaks 24-36 hours after the onset of bleeding and can last up to 72 hours, often with nausea, vomiting, diarrhoea, low back pain, headache or fatigue. Its worldwide prevalence exceeds 60% in women under 25 years and reaches 93% in adolescents, and it is the most frequent cause of school and work absenteeism in womenunder 30.

The main mechanism is myometrial ischaemia caused by excessive uterine contractions driven by prostaglandins. First-line treatment consists of non-steroidal anti-inflammatory drugs and oral contraceptives, but these cause side effects and fail in 20-25% of women, so safer conservative alternatives are needed.

Exercise is the reference conservative treatment for primary dysmenorrhea, but published programmes are heterogeneous and no detailed protocol exists. Heat therapy reduces menstrual pain by 36.5-50%. Radiofrequency (RF) produces controlled deep heating and has reduced pain in chronic pelvic pain and anorectal pain syndromes. Abdominal RF has reduced pain in primary dysmenorrhea compared with superficial heat. No trial has compared intravaginal RF with exercise, alone or combined, in primary dysmenorrhea.

Hypothesis. RF-based conservative treatment is effective in improving the symptoms of primary dysmenorrhea, could act as an adjuvant to exercise-based treatment, and could reduce the use of analgesic medication.

3. Objectives

General objective. To compare the effectiveness of radiofrequency-based treatment with exercise-based treatment on the symptoms associated with primary dysmenorrhea.

Specific objectives. To evaluate the effect of radiofrequency, physical exercise and their combination on:

- pain associated with primary dysmenorrhea;
- consumption of analgesic drugs;
- quality of life;

- sexual function.

4. Trial design and setting

Randomised clinical trial with three parallel arms (1:1:1): radiofrequency (RF), physical exercise (EF) and combined RF + EF. The study is conducted at NG Clínicas - Clínica Ginecológica Juana Lafaja Mazuecos (Elche, Spain), which has a gynaecology room suitable for assessment and RF treatment and a space for group exercise. A signed site authorisation is in place. The study follows the Declaration of Helsinki and Spanish legislation (Royal Decree 223/2004 and Law 14/2007 on Biomedical Research). The study was planned to start in May 2025, with an estimated duration of 2 years.

5. Participants

Women attending the gynaecology clinic with a diagnosis of primary dysmenorrhea are invited to participate, as well as women reached through social media (Instagram, Facebook, TikTok and LinkedIn) with a video explaining the study aim, target population and eligibility criteria. At the clinic, the gynaecologist explains the study in detail and invites eligible women to take part.

Inclusion criteria:

- Women aged 18-35 years with a regular menstrual cycle (24-35 days).
- Normal genital ultrasound without clinical signs of organic disease.
- Primary dysmenorrhea in all menstrual cycles since menarche.
- Menstrual pain of 5 or more on a visual analogue scale (VAS).
- Body mass index between 20 and 30.

Exclusion criteria:

- Gynaecological findings of secondary dysmenorrhea (pelvic inflammatory disease, uterine fibroids, polyps, endometriosis, adenomyosis, chronic or subacute cervicitis, etc.).
- Pregnancy.
- Breastfeeding at the time of the study.
- Use of an intrauterine contraceptive device.
- Physiotherapist-supervised pelvic floor muscle training, or RF to the pelvic region, in the previous 12 months.
- Inability to understand the study information (cognitive impairment).
- Peripheral or central neurological disorders.
- Previous pelvic surgery.
- Skin disease or wounds in the treatment area.
- Active urinary tract and/or vaginal infection.

6. Study procedures

The first contact is always made by the same investigators (C. Orts and C. Salar), who explain the study and provide the participant information sheet and informed consent form (Part C). After consent, participants complete an ad hoc questionnaire (sociodemographic data, gynaecological history, dysmenorrhea, menstrual pain and drug use) and validated questionnaires on quality of life, sexual function and premenstrual symptoms. They also receive a diary to record the date, time, type and amount of analgesics taken for dysmenorrhea during every menstrual cycle of the intervention period.

Baseline ultrasound. The gynaecologist performs a transvaginal ultrasound (ESAOTE A50, E3-12 endocavitary probe) in lithotomy, with an empty bladder, during the proliferative phase of the cycle, to exclude organic causes of dysmenorrhea. It records uterine position (anteflexion or retroflexion, grades 1-3), uterine length and thickness, endometrial thickness, ovarian volume, morphology and position, anterior and posterior compartment sliding, and the thickness and morphology of the uterosacral ligaments.

Pelvic floor muscle assessment. The same investigators then assess pelvic floor muscle (PFM) function (section 9).

7. Randomisation and blinding

An investigator blinded to the previous assessments (S. Montero Navarro) allocates participants at random to the three groups using SAS 9.4 (SAS Institute, Cary, NC, USA) with 1:1:1 allocation. The assigned treatment is kept in sealed, opaque envelopes identified by a number. One physiotherapist (C. Orts) delivers RF and another (C. Salar) delivers the exercise programme. Participants cannot be blinded to treatment. The statistician (J. Sánchez-Más) is blinded to the intervention and to data collection.

8. Interventions

8.1 Radiofrequency

Capacitive electric transfer with a Capenergy C500 Urogyne device, designed for urogynaecological dysfunctions, with tissue temperature regulated by a sensor, three frequencies (0.8, 1 and 1.2 MHz) and 310 W power. It has an active capacitive electrode used intravaginally with a probe cover and water-soluble gel, and a dispersive return plate. Each session includes two applications:

- **First application (athermic, 10 min):** passive plate on the lumbar region and active plate on the abdomen, to relax the musculature and allow drainage.
- **Second application (20 min):** passive plate and MJS electrode with a covered, lubricated probe. In a retroflexed uterus, the passive plate is placed on the lumbosacral region; in an anteflexed uterus, on the abdomen. The electrode is directed towards the vaginal fornix according to uterine position. RF is applied at a high thermal sensation (up to 43-44 °C) for 20 minutes, sweeping from 3 to 9 o'clock.

The temperature reached and the energy delivered (kJ) are recorded after each session. Eight sessions are given at 7-day intervals. Tolerance to temperature is monitored continuously and intensity or temperature is reduced if the participant reports pain or discomfort. In case of an adverse reaction (burn, significant irritation or persistent pain), the procedure is stopped and appropriate care is provided.

8.2 Physical exercise

A supervised programme of core and pelvic floor exercises, based on the baseline assessment of strength, endurance and fatigability, delivered twice a week for 8 weeks (16 sessions of 45 minutes) in groups of up to 8 participants by a physiotherapist experienced in therapeutic exercise. Sessions combine strength and aerobic work with relaxation exercises, adapted from yoga, aerobic and strength programmes. Two different sessions are used each week to promote adherence and motivation, and intensity increases after week 4. The session-by-session programme is given in Appendix A1.

8.3 Combined intervention

Participants in the combined group receive both the RF protocol and the exercise programme.

8.4 Adherence

Participants who miss any RF session, or whose attendance at supervised sessions is below 80%, are considered non-compliant with the protocol; they are included in the intention-to-treat analysis.

9. Outcomes

All outcomes are assessed at baseline, 1 week, 6 months and 1 year after the end of the intervention.

- **Pain intensity:** visual analogue scale, 0-10 cm (0 = no pain, 10 = maximum pain).
- **Pain quality:** McGill Pain Questionnaire (one descriptor chosen from each of 20 subclasses, each with a specific score).
- **Analgesic consumption:** diary of analgesic intake (date, time, type and amount) during each menstrual cycle of the intervention.
- **Quality of life:** EuroQol-5D (five dimensions at three levels: mobility, self-care, usual activities, pain/discomfort and anxiety/depression) plus a visual analogue scale of health status.
- **Sexual function:** Female Sexual Function Index (FSFI), previous 4 weeks; a score of 26.5 or lower indicates sexual dysfunction.

- **Premenstrual symptoms:** Premenstrual Symptoms Screening Tool (PSST), 14 items based on DSM-IV criteria (score 0-42; higher = more severe), plus impact on five areas of functioning.
- **Pelvic floor muscle function:** after voiding and 3 minutes of seated rest, in lithotomy. Digital assessment using the PERFECT scheme: function (best of 3 attempts, 0-3), strength (modified Oxford scale 0-5, best of 3), static endurance (seconds to fatigue, mean of 3) and dynamic endurance (maximum contractions in 10 s, mean of 3). Intravaginal manometry with an air-filled probe connected to a Phenix Liberty device (Electronic Concept Lignon Innovation, Montpellier, France): resting tone and maximal pressure held for 10 s (mean of 3).
- **Treatment satisfaction** (end of treatment only): five-point Likert scale (1 = very dissatisfied to 5 = very satisfied).

10. Schedule of assessments

Assessment	Baseline	Intervention (8 weeks)	1 week post	6 months post	1 year post
Eligibility, consent, ad hoc questionnaire	X				
Transvaginal ultrasound	X				
Randomisation (1:1:1)	X				
Radiofrequency (8 weekly sessions)		X			
Exercise (2 sessions/week × 8 weeks)		X			
Analgesic diary		X			
VAS menstrual pain	X		X	X	X
McGill Pain Questionnaire	X		X	X	X
EQ-5D	X		X	X	X
FSFI	X		X	X	X
PSST	X		X	X	X
PFM function (PERFECT, Oxford, manometry)	X		X	X	X
Treatment satisfaction			X		
Adverse events		X	X	X	X

11. Sample size

The sample size was based on a previous study showing a statistically significant reduction in pain (VAS, primary variable) in patients with chronic pelvic pain who received an RF programme similar to the one proposed here. Assuming 25% attrition, $\alpha = 0.05$ and power of 80%, the required sample is 120 women (40 per group).

12. Data management and confidentiality

Data are stored on the OneDrive cloud of Fundación Universitaria San Pablo CEU (FUSP-CEU), with password access restricted to the investigators responsible for analysis, extraction and handling (J. Sánchez-Más, C. Salar Andreu and C. Orts Ruiz). Data are identified by a code without identifying information and processed under Regulation (EU) 2016/679, under the responsibility of FUSP-CEU. Data that could link participants to their responses are kept only for the duration of the project (estimated at 2 years from ethics approval) and then permanently erased with Eraser software.

13. Ethics and dissemination

The protocol, information sheet and consent form were approved by the Biomedical Research Ethics Committee of Universidad CEU Cardenal Herrera (report CEEI25/670, 7 April 2025). Written informed consent is obtained before any study procedure. Any substantial change will be submitted to the committee as an addendum. Results will be submitted to peer-reviewed journals.

Appendix A1. Exercise programme (16 sessions)

Unless otherwise stated, exercises are performed for 10 repetitions with transversus abdominis activation and pelvic floor awareness. Session 1 is individual; the rest are group sessions.

Sessions	Exercises
1 (individual)	Treatment-room session: anatomical concepts, breathing and exercise technique, checked by digital testing. Sustained and fast contractions and apnoea time are prescribed according to the baseline assessment.
2, 4, 6	Supine with knees bent: self-elongation with transversus and pelvic floor activation in resisted expiration; the same with glute bridge, and with unilateral hip flexion and knee extension. The same in apnoea after two full breaths, held for 10 s, with bridge variations. Supine, legs at 90° with a ball between the knees: hip and knee flexion-extension with adductor activation. Side-lying hip abduction-adduction (slow full range and fast small range), foot circles and hip-knee flexion-extension. Sustained and fast contractions sitting on a fitball. Pelvic awareness and mobility on the fitball (circles and figures of eight).
3, 5	Pelvic awareness and mobility on the fitball; sustained and fast contractions on the fitball; apnoea with self-elongation for 10 s on the fitball, with single-leg raise. Quadruped: pelvic tilt; contralateral arm and leg raise in resisted expiration; hypopressive exercise with arm flexion and leg extension. Pelvic mobilisation and dynamic stretching ending with child's pose and posterior chain stretch.
7, 9	Standing pelvic awareness and mobility; standing sustained and fast contractions; balance and motor control on stable and unstable bases and on a foam roller; deep squat; isometric squat; alternating lunges (10 per side). Supine glute bridge progressions in resisted expiration; hip and knee flexion-extension with a ball. Active stretching, relaxation and body awareness.
8, 10	Supine pelvic awareness with sustained and fast contractions; apnoea exercises with bridge progressions; side-lying hip exercises at 45°; quadruped hypopressive exercise in downward-dog position with leg raises. Planks of 60 s with 30 s rest (forearm, straight arm, side planks, alternating limb raises). Crunches in expiration, with lateral flexion and with trunk rotation; obliques. Active stretching and relaxation.
11, 13	Single-leg glute bridge progressions; hip and knee flexion-extension with a ball in three phases. Planks of 90 s with 30 s rest, including mountain climbers. Active stretching and relaxation.
12, 14	Standing pelvic awareness; standing sustained and fast contractions, also on one leg. Balance and motor control with kettlebell on stable and unstable bases; deep squat, isometric squat and alternating lunges with kettlebell. Quadruped hypopressive exercise in downward-dog position with leg movements. Crunches with kettlebell, lateral and rotational crunches, obliques with weight. Active stretching and relaxation.
15	Single-leg glute bridge progressions; hip thrust with kettlebell; hip and knee flexion-extension with a ball in three phases. Planks of 90 s including mountain climbers. Downward-dog leg raises with hip and knee extension and flexion-extension. Active stretching and relaxation.
16	Standing pelvic awareness; sustained and fast contractions while walking; skipping. Balance and motor control with kettlebell swing on stable and unstable bases; deep squat, isometric squat and alternating lunges with kettlebell; burpees; box jumps or step-ups. Crunches with kettlebell, lateral and rotational crunches, obliques with weight. Active stretching and relaxation.

Summarised translation of Annex 8 of the ethics-approved protocol.

PART B. STATISTICAL ANALYSIS PLAN

1. General principles

- Analyses will be performed in IBM SPSS Statistics version 29 by an investigator (J. Sánchez-Más) blinded to the intervention and to data collection.
- Results will be analysed by intention to treat: all randomised participants in their allocated group, including those who did not complete the protocol.
- The significance level is 5% (two-sided).
- Normality will be assessed with the Kolmogorov-Smirnov test.

2. Between-group comparisons

Comparisons between the three groups will use analysis of variance (ANOVA) or the Kruskal-Wallis test, depending on the distribution. Associations between categorical variables will be analysed with the χ^2 test and Fisher's exact test.

3. Within-group comparisons

Within-group changes will be evaluated with the paired Student's t test or the Wilcoxon test for continuous variables, and with the McNemar test or Bowker's test of symmetry for categorical variables.

4. Repeated-measures analysis

Data will also be evaluated with repeated-measures ANOVA to estimate simultaneously the effect of the three study groups (between-group effect), the assessment time points (within-group effect) and the group × time interaction for each variable. The time points are baseline, 1 week, 6 months and 1 year after the end of the intervention.

5. Sample size

See Part A, section 11: 120 participants (40 per group), assuming 25% attrition, $\alpha = 0.05$ and power of 80%.

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 (CEEI25/670; original in Spanish). Personal identification numbers have been redacted for public posting.*

PARTICIPANT INFORMATION SHEET

Study title: Effectiveness of radiofrequency and physical exercise on symptoms associated with primary dysmenorrhea. Randomised clinical trial.

Principal investigator: Dr 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 or gynaecologist.

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?

Dysmenorrhea is a set of symptoms in the pelvic, lumbar and abdominal region that occur during menstruation, and sometimes before it, and that often make daily activities difficult.

The aim of the study is to find out the effectiveness of physiotherapy treatment based on activation of the pelvic floor muscles through heat induced by radiofrequency and through physical exercise for improving the symptoms associated with dysmenorrhea. These are non-invasive and painless treatments that have been very effective in treating painful symptoms affecting the muscles of women of reproductive age.

How will the study be carried out?

You will first be assessed by the gynaecologist, Dr Juana Lafaja, at the Juana Lafaja Mazuecos gynaecology clinic, Calle Beethoven 20, bajo 3, 03203 Elche (Alicante). You will have an abdominopelvic ultrasound assessment and will complete questionnaires to collect information on gynaecological data, pain associated with primary dysmenorrhea, stress and quality of life.

Next, physiotherapists experienced in pelvic floor care will carry out a vaginal assessment of pelvic floor muscle strength. Participants will be assigned at random to one of the three treatment groups of the study: heat stimulation (radiofrequency with an intravaginal electrode) (group 1), physical exercise (group 2), or radiofrequency with an intravaginal electrode plus physical exercise (group 3).

The study will begin in May 2025. Radiofrequency will consist of 8 sessions of 30 minutes, with an interval of 7 days between sessions. Physical exercise will consist of an exercise programme including pelvic floor activation, supervised by a physiotherapist, twice a week, for 45 minutes each day, over 8

weeks. You will be advised to continue the exercises at home, and adherence to the home programme will be monitored through a paper diary, although following it is not a requirement.

Who can take part?

To take part you must be aged between 18 and 35 years, have had menstrual pain since your first period (menarche), have no clinical sign of organic disease, have pain considered intense (this will be assessed at the first visit) and have a body mass index of 20-30 (normal weight or slight overweight).

You cannot take part if you are pregnant or breastfeeding during the study (if you become pregnant during the study, your participation must stop), have an intrauterine contraceptive device (IUD), have been diagnosed with secondary dysmenorrhea (pelvic inflammatory disease, uterine fibroids, polyps, endometriosis, adenomyosis, chronic or subacute cervicitis, etc.), have done pelvic floor muscle exercises supervised by a physiotherapist or received radiofrequency to the pelvic area in the last 12 months, have peripheral or central neurological disorders, have had previous abdominopelvic surgery, or have wounds or skin conditions in the abdominopelvic area or active urinary tract and/or vaginal infections.

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.
- Once you have agreed to take part, attend a first clinical review consisting of an abdominovaginal ultrasound, an assessment of pelvic floor muscle strength, and questionnaires on sociodemographic data (age, weight, occupation, education), gynaecological history and dysmenorrhea pain, and its impact on your quality of life, sexual function and stress, using questionnaires validated for this type of study. You will also be given a form to record the painkillers you take for menstrual pain, noting the time, type and amount, during every cycle of the intervention.
- Be randomly assigned to one of the three intervention groups.
- Attend the same clinical review again 1 week after finishing treatment, and 6 months and 1 year after finishing treatment.

At the end of treatment you will be asked to rate your satisfaction with the intervention on a scale from 1 (dissatisfied) to 5 (very satisfied).

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 43-44 °C, which reduces the risk of burns and collagen changes, working within safe temperatures.

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 reduce pain and improve vaginal condition, and therefore have a positive impact on quality of life, stress and sexual function.

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 the symptoms of dysmenorrhea.

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

If you do not take part, your gynaecologist will propose other individualised treatment strategies based on your clinical history and examination.

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 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. The processing, communication and transfer of personal data of all participants will comply with the 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 collected 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, modification, objection and cancellation of data by contacting your study doctor. 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 the study described or for scientific publications, always maintaining confidentiality in accordance with current legislation.

The data collected will never be used for any other purpose; all data will be kept only for the duration of the study, estimated at 2 years.

Whom can I contact if I have questions?

If you have any questions, please contact Cristina Orts Ruiz (Universidad CEU Cardenal Herrera) at +34 965 42 64 86, extension 403. 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 physical exercise on symptoms associated with primary dysmenorrhea. 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, 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 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.
9. I sign this information and consent document voluntarily to express my wish to take part in this research study on RADIOFREQUENCY AND THERAPEUTIC PHYSICAL EXERCISE FOR THE TREATMENT OF DYSMENORRHEA 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
Elche, on …… of …… 202..

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____