RESEARCH PROTOCOL

Study identification data

Study Title

Conservative approach to dysfunctional pain in women

Study version number and date

V.01 (01-12-2021)

Promoter and direction

Borja Perez Dominguez. C/Valencia, 17. Low. Gillet (Valencia). 46149

Principal Investigator and Director

Borja Perez Dominguez. C/Valencia, 17. Low. Gillet (Valencia). 46149

Service or Unit

Gynecology/Rehabilitation

Centers where the study is planned (multicenter studies)

Hospitals of Sagunto, La Plana, IMSKE Valencia and University of Valencia

Study Summary

Study that will seek to compare the effects of the implementation of a therapeutic education program in women suffering from dyspareunia for a period of more than three months who do not have any previous medical condition that can logically explain this condition. The effects of three groups will be compared; one that attends face-to-face workshops, another that will receive access to a website where the educational content will be, and a third that will serve as control.

Study Introduction

This research project is entitled "Conservative approach to the patient with dysfunctional pain in the pelvic floor in women". It will be carried out both by researchers from the University of Valencia and by external researchers from other hospitals.

We understand dysfunctional pain as pain that stops fulfilling the function of "alarm signal" and that stops responding to a nociceptive stimulus (1). This alarm signal can be triggered by previous pathologies, such as endometriosis (2) or musculoskeletal conditions such as muscle hypertonia (3) or neuralgia (4).

Despite this, this pain can also originate without the existence of any of the previous conditions, therefore without having a clear origin that can be addressed through treatment. In the pelvic floor, this dysfunctional pain can come to take different names, among which we highlight "dyspareunia" and "vestibulodynia" (5).

“Dyspareunia” is a term derived from the Greek that means lovers who do not fit together (6), and it is a sexual disorder that is defined by the presence of pain and discomfort during the sexual act, in addition to being predominantly associated with the attempt or achievement of sexual intercourse. complete vaginal penetration (7). Prevalence levels range from 3% to 43%, and vary depending on different cultures and settings (6) (8).

Study justification

The lack of a good educational level in women's health disorders can lead to misinterpretations about normality, and these end up causing both sexual and emotional repercussions (8). It is a common misconception that intercourse can sometimes be painful, and many women are forced to continue intercourse even in pain, even having to clench their teeth.

Because of this, women who suffer from dysfunctional pelvic floor pain develop clinically relevant comorbidities, especially psychological ones, such as depression, anxiety or erotophobia (6) (8) .

For this reason, the treatment of dysfunctional pain with therapeutic educational sessions is proposed so that women who suffer from dyspareunia are able to better understand the processes of this condition and, possibly, solve it.

Study Objectives

The main objective of this study is to compare the effects of implementing a therapeutic educational program on pelvic floor pain and dysfunction in patients with dysfunctional pain. This program will be administered both in person at workshops organized in different centers, and online through a web platform.

As a secondary objective, the adherence levels of each of the proposed educational programs will be analyzed.

Material and methods

Design

Randomized controlled clinical trial.

Disease o Study population and total number of subjects

Women with dysfunctional pelvic floor pain that cannot be explained by another underlying medical cause

Selection criteria (inclusion and exclusion)

Women who (1) are of legal age, (2) have suffered from dyspareunia for more than 3 months and (3) do not have any medical condition that logically explains the presence of pain

Main variables

Level or intensity of pain, evaluated using subjective perception scales (Visual Analogue Scale or VAS).

Secondary variables

Other questionnaires related to dysfunctional pain; Pain Catastrophizing Scale to quantify the patient's individual experience of pain, the Multidimensional Pain Inventory to measure the impact of pain on the patient's life, the Survey of Pain Attitudes related to the patient's beliefs about pain, and the Female Sexual Function Index related to the patient's sexual function.

The levels of adherence to the different programs will also be evaluated, established by the percentage of sessions completed based on the total number of sessions offered.

Interventions/procedures to be performed

Initial phase of patient recruitment from various hospital centers and by broadcasting with an informative video on RRSS through the official profiles on Instagram, Facebook and Twitter of the University of Valencia and the Illustrious College of Physiotherapists of the Valencian Community. The hospital centers that will initially be considered for obtaining the sample are the La Plana and Sagunto Hospitals and the IMSKE Hospital in Valencia. After this first phase, and using the established inclusion and exclusion criteria, randomization of all the participants into three different groups. The randomization method will be a simple randomization performed through computer software.

One group (1) will receive a therapeutic education program on pelvic floor pain and dysfunction in person as workshops held at collaborating centers, a second group (2) will receive access to a web platform where they can view as online content this same educational program and a third group (3) that will serve as control.

Both group (1) and group (2) will receive the same educational content, the only thing that will change is the modality in which they can access it, face-to-face through workshops given by specialist trainers, or access to an online platform where the contents previously recorded by these same trainers will be.

a "forum" will be opened on the same website where they can comment on their doubts). Each workshop will last approximately one hour, and the schedule will be established according to the possibilities of the participants.

The web platform will be developed thanks to a researcher who already has an online studio where she teaches therapeutic exercise classes, available athttps://mariaplazacarrasco.com. Participants who have been randomized in the online group will be given an access code to be able to enter the online space where they will have both the audiovisual material that has been previously developed by the researchers and a forum where they can discuss their doubts.

Regarding the control group, initially the participants of this group will not receive any of the two previous interventions, this group will serve to establish how the condition is maintained without a therapeutic approach. Once the intervention has finished and the post measurements have been collected, the participants of this group will also be given access to the online study so that they can view the contents and comment through the forum.

Work calendar

Calendar	**Exercise**	**Place**	**Responsible**
October to December 2021	Subject Selection	H. La Plana, H. IMSKE, H. Sagunto, University of Valencia	Jose Casaña Granell, Borja Pérez Domínguez, Aida López Brull
December 2021 to January 2022	Measurements prior to the start	H. La Plana, H. IMSKE, H. Sagunto,	Aida Lopez Brull, Cristina Blasco

	of the intervention	University of Valencia	Ortiz, Marta Morales Baixauli
January to March 2022	Intervention. Educational sessions on dysfunctional pain	H. La Plana, H. IMSKE, H. Sagunto, University of Valencia and online modality	Aida Lopez Brull, Cristina Blasco Ortiz, Marta Morales Baixauli
March to April 2022	Post-intervention measurements	H. La Plana, H. IMSKE, H. Sagunto, University of Valencia and online modality	Aida Lopez Brull, Cristina Blasco Ortiz, Marta Morales Baixauli
April 2022	Preparation of a scientific article with the results obtained from the research		Aida Lopez Brull

Statistical analysis of data: equal to or less than 0.05)

The study design aims to collect pre and post measurements with various interventions. To do this, since these are pre and post measurements with several groups, a factorial ANOVA will be carried out, a repeated measurement factor (time) and a factor between groups (intervention).

The changes that are intended to be achieved are, with respect to the main variable, a significant reduction in the values of the VAS scale that corresponds to an improvement in terms of pain intensity. Regarding the secondary variables, significant changes in the score of the questionnaires on dysfunctional pain and sexual function that indicate clinical improvements regarding the impact of pain on the life

of the participant and the beliefs about the pain of the same, and on the levels of adherence, find high values to be able to relate the results obtained with the implementation of the program.

Sample size calculation and sampling procedure

The sample size was determined using the G-Power computer program. An a priori size calculation was performed with an effect power of 80% and an alpha error of 0.05. It was determined that the sample must have a minimum of 48 participants, and that each group must have a minimum of 16. Taking into account possible drop-outs, it was determined that a minimum sample of 60 participants and 20 participants for each group.

Ethical aspects and data confidentiality

This research deals with the implementation of an educational program on dysfunctional pelvic floor pain in women. It does not involve an invasive or aggressive intervention that could cause negative effects on the participants. In addition, if the final result is positive, there will be a tool that is easy to implement daily for the treatment of patients with this problem.

The subjects will be informed at all times of how the research will proceed, and before being included in the study sample they will be required to give their consent, both verbal and written, to participate in this research.

We will ensure that the data provided by patients is strictly confidential. Patients will be coded to ensure their anonymity and both the principal investigator and the person in charge of processing the statistical data will be blinded to the group assignment and to which patient corresponds to which value.

During the development of the investigation there will be no interference with regard to medical action. Once the study is over, and if the result is positive, the medical staff will be provided with the material with which the research has been carried out so that they can use it in their daily practice.

Sources of funding

The study has sufficient material and human resources to carry it out. Two researchers will coordinate its development, and the rest of the researchers will be in charge of carrying out the measurements prior to the start of the intervention, implementing the educational program and finally performing the measurements again. No medication will be supplied and there is no need for funding to carry out this research.

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