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Effect of the interaction between physical and mental health treatments in women with chronic pelvic pain: A randomized controlled trial

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ABSTRACT

Objectives: To prospectively evaluate a mindfulness protocol and pelvic floor physical therapy (PFPT) for women with chronic pelvic pain (CPP) who were otherwise physically and mentally healthy, comparing the effectiveness of the treatments separately and together.

Materials and Methods: Women with CPP were randomized into two groups. Each group initially underwent a mindfulness protocol or PFPT (including electrotherapy, biofeedback, trigger point massage, and basic pelvic kinesiotherapy guidance), being switched to the other therapy after the first intervention, so all participants underwent both interventions. Participants were evaluated at 4 time points: Baseline, after each intervention and 8 months after the final therapy using the SF-36, the Mindful Attention Awareness Scale (MAAS), the visual analog scale (VAS), pelvic assessment, and electromyography questionnaires.

Results: Of 49 included women, 38 participated in both interventions and completed all 4 evaluations. In 7 physical examination and biofeedback scores, the group performing PFPT first achieved significant gains ($p<0.05$) immediately after the first intervention, while the group starting with mindfulness achieved significant gains only after the second intervention. In other 6 physical examination and biofeedback scores, both groups achieved significant gains immediately after the first intervention. In the MAAS, VAS, and in 4 domains of the SF-36, the sum of the interventions showed progressively significant improvement. At follow-up, gains were sustained in more than 85% of the 29 domains.

Conclusion: The results suggest that performing both therapies simultaneously could optimize gains in quality of life, pain management, and pelvic floor health in women with CPP.

Keywords: Chronic pain; mindfulness; pelvic pain; physical therapy

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INTRODUCTION

Chronic pelvic pain (CPP) in women is a complex multifactorial pain syndrome that is commonly seen in clinical practice. It is an important health problem and a source of disability. It is defined as non-cyclic pain from a physical and emotional experience that lasts for at least 6 months and is severe enough to cause functional disability and require treatment.[1-4]

The International Classification of Diseases-11 defines all pain lasting ≥3 months to be chronic, and although this new definition significantly increases the number of women suffering from CPP, outdating existing epidemiological data, it may prove beneficial for early diagnosis and treatment.

Very few studies have included women with symptoms <6 months, and given that women tend to wait a long time before seeking help, this represents a challenge: Women suffering from CPP describe their health journey as long and frustrating, involving countless specialists who often dismiss their pain. A common story heard from these women is their difficulty finding professionals who value their complaint and symptoms.[5,6]

CPP causes central nervous system changes that perpetuate the perception of pain even in the absence of the lesion that initiated the pain. Myofascial trigger points, which are observed in CPP, are characterized by abnormal contractions of focal muscle, which appear as tense bands that often do not correlate with the presence of injury and may be associated with varying degrees of sensitivity and motor dysfunction. These myofascial trigger points are classified as active or latent, depending on the presence or absence of spontaneous pain, respectively, when the muscle is at rest, and as referred pain when distant from the myofascial trigger points. Thus, pelvic floor dysfunction is often associated with CPP, since myofascial structures, viscera, and the central nervous system are interconnected.[2,3,6,7-11]

Mindfulness, self-awareness retraining similar to meditation, has been clinically applied in medicine as an alternative therapy for various health conditions, such as CPP.[12,13] It has been suggested that stress reduction influences the up- and downregulation of pain responsiveness inherent to central sensitization and neuroendocrine pathophysiology of the skin.[5,6]

In another treatment approach that differs from past decades, the prevalence of myofascial disorders in CPP, which was formerly estimated at around 8 percent, is now considered 85-90%, and physical therapists more commonly involved in the assessment and multidisciplinary treatment of CPP and pain management. Pelvic floor physical therapy (PFPT), an evidence-based and globally accepted therapy for treating of many pelvic floor disorders, has a low risk of adverse effects, is non-invasive, and has a moderate cost.

In this study, we propose an innovative approach: Evaluating the effectiveness of a multidisciplinary treatment for women with CPP that consists of PFPT and a mindfulness protocol.

Thus, rehabilitation has the tools to deal with these neuroplastic changes, including top-down cognitive interventions (mindfulness) and bottom-up physical interventions (PFPT) that induce neuroplastic changes in areas distributed throughout the nervous system and affect CPP outcomes.[14]

MATERIALS AND METHODS

Trial Design

This was a parallel-group controlled trial with equal randomization (1:1 for 2 groups) conducted in a single center in Brazil. The trial is registered at the Brazilian Registry of Clinical Trials (ID13375).

Patient Population

A total of 64 women were recruited from the pelvic dysfunction and CPP outpatient clinic of the hospital urology sector. Eligible participants included women >18 years of age with CPP. The exclusion criteria were pregnancy in the last 12 months, active infectious diseases, currently cancer treatment, cognitive impairment that impeded understanding of the treatment guidelines and/or inability to respond to the questionnaires.

Outcomes

The primary outcome was the improvement (gains) in quality of life, pain management, and pelvic floor health from baseline to 8 months after the final therapy as measured by SF-36, Mindfulness Attention Awareness Scale (MAAS), visual analog scale (VAS), physical examination, and biofeedback questionnaires.

Sample Size

To detect a difference between groups of one standard deviation (standardized effect size considered moderate to large) for any of the evaluated outcomes, a sample size of 22 patients per group was initially calculated. Considering α=0,05, a power of 90%, and 10% of losses, 25 patients were required for each group (50 patients in total). The sample size calculation was performed on WINPEPI version 11.65.

Randomization and Sequencing of Assessments During the Survey

A computer-generated list of random numbers prepared by an investigator with no involvement in the trial was used for allocation of the participants to 1 of 2 treatment groups, and the allocation sequence was concealed in sealed envelopes.

Study participants were initially randomized to a mindfulness protocol (n=25) or PFPT (n=24) for 8 weeks (Figure 1). Both groups received basic guidance about the pelvic floor and how to recognize and locate it in their own body. All patients and physicians were aware of the allocated arm.

PFPT involved individualized treatment and the mindfulness protocol involved group therapy, both of which were performed once a week for 60 minutes by a pelvic physical therapist specializing in women's health and a professional mindfulness specialist, respectively. Patients were reassessed a second time (T2) after undergoing one of the treatment interventions. Following the first treatment, the protocols were reversed: The group of patients who had undergone PFPT underwent the mindfulness protocol, and vice versa. The participants were reassessed at a third time point (T3) after having undergone both treatment interventions, and again 8 to 10 months after the final intervention (T4).

Anamnesis and Physical Assessment

A researcher assessed the participants at 4 points during the study using a modified structured anamnesis form from the International Association for the Study of Pain, while another performed physical and electromyographic assessment. The latter were based on physical therapy assessment sequences suggested by Berghmans et al.[15], a modified Glazer scale, and European Union Surface ElectroMyoGraphy for Non-Invasive Assessment of Muscles (SENIAM) recommendations.

In the anamnesis, the patients provided information about their sociodemographic profile and the possible underlying pathology or primary cause of CPP. Through structured questionnaires validated for the Portuguese language, the patients also reported on quality of life (SF-36) and pain (VAS regarding activities of daily living: Leisure, work, during and after intercourse, urination, defecation, and long periods of sitting), and they also answered the MAAS.

The physical examination began with abdominal and vulvar assessment (respiratory type, abdominal contractures, and surgical scars) in the lithotomic position with an empty bladder. The evaluation consisted of intravaginal, single-digit gloved palpation by the examiner, observing and respecting each patient's pain condition around the pelvic "clock", observing active and latent trigger points for referred suprapubic, abdominal and/or lumbar pain.[9,16,17]

Pain mapping data provided an individualized pain profile for each participant, following Jantos.[10] Trigger points were evaluated in superficial and deep perineal musculature around the clock. As recommended by SENIAM and following Bertotto et al.[17], an average of 3 maximum voluntary contractions was used.

Through physical palpation, the degree of perineal muscle

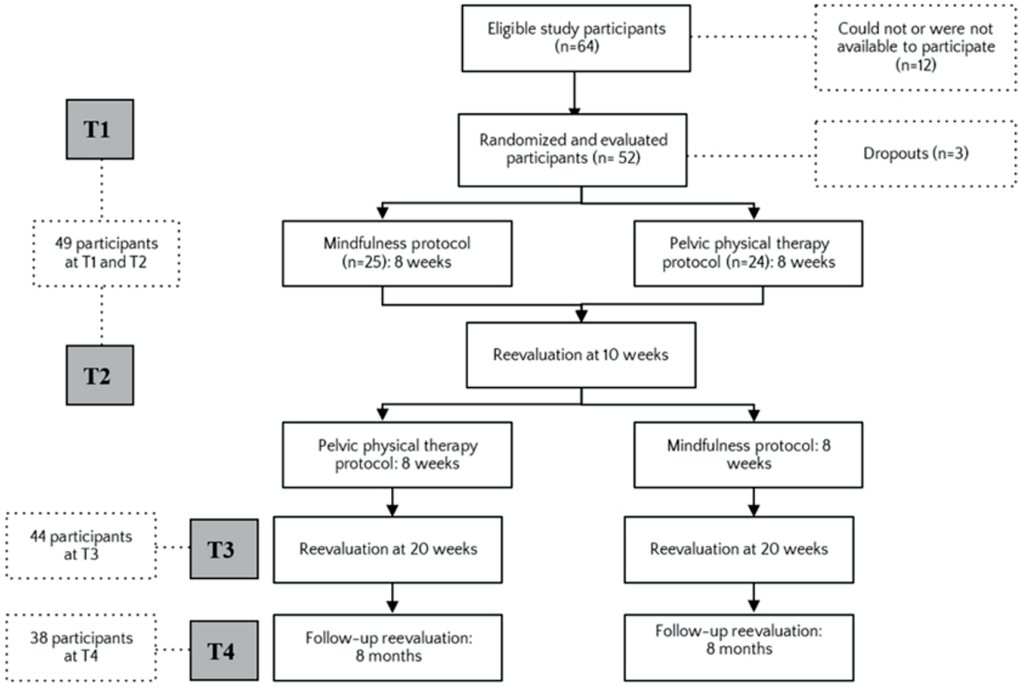

Figure 1. Patient inclusion and intervention flowchart
T1: Pretreatment; T2: First assessment; T3: Assessment after undergoing both treatment interventions; T4: Late comparison at follow-up

contraction (modified Oxford scale: 0-5s), sustained for "n" seconds, pre-contraction, fast contraction, and relaxation were evaluated.

In addition, the electrical activity of the pelvic floor muscles at rest and at maximum voluntary contraction was evaluated by electromyography, according to a modified Glazer protocol.[18]

Mindfulness

In the present study, the mindfulness protocol involved 2-hour weekly meetings for 8 weeks. The classes were led by a specialized mindfulness instructor from the Mente Aberta Institute of the Universidade Federal de São Paulo (Brazilian Center for Mindfulness and Health Promotion). This institute uses a mindfulness-based health promotion protocol based on the mindfulness-based stress reduction model. Mindfulness-based health promotion includes exercises from programs such as mindfulness-based cognitive therapy, mindfulness-based relapse prevention, and Breathworks' Mindfulness for Health. A main theme was presented in each of the 8 weekly sessions (Supplementary Table S1).

Pelvic Floor Physical Therapy

PFPT was based on assessment and treatment with electromyography biofeedback (Supplementary Table S2). It was performed using an intravaginal probe appropriate to the diameter of the vaginal canal of each patient so that pain or discomfort was not worsened.

To calibrate the contraction in biofeedback, an average of 3 maximum voluntary contractions was used, following Bertotto et al.[17] and SENIAM recommendations, a reference protocol for musculature in general. A modified Glazer protocol was also used to guide contraction and relaxation: With initial rest, fast contraction, sustained contraction of 30 seconds, and final rest.[18]

As shown in the Supplementary Table S2, electrotherapy was used with currents of 3 Hz/250 µs for 20 minutes and 50 Hz/250 µs according to the individualized contraction time of each patient.[10,19]

All patients had weekly individual orientation and homework: Intravaginal massage of trigger points, the use of heat, kinesiotherapy (relaxation and contraction of perineal muscles, breathing associated with contraction of the transversus abdominis), and pelvic tilt exercises.

The patients were included in a WhatsApp group in which they could interact with the other participants and the physical therapist, in addition to individual private contact with the therapist.

All participants were given the same anatomical guidance about the pelvic floor, such as recognizing, feeling, contracting in everyday situations.[9]

Statistical Analysis

The data were entered into Microsoft Excel and later exported to IBM SPSS Statistics 20.0 for statistical analysis. Categorical variables were described as frequencies and percentages. The normality of quantitative variables was assessed using the Kolmogorov-Smirnov test. Normally distributed quantitative variables were described as mean and standard deviation, while asymmetrically distributed variables were described as median, minimum, and maximum. Categorical variables were associated using the chi-square test or Fisher's Exact test according to the number of categories and expected frequencies at the initial time point. For baseline comparison, normally distributed quantitative variables were compared using Student's t-test for independent samples, while asymmetrically distributed variables were compared using the Mann-Whitney U test. Generalized estimating equation models were used to compare the evolution of the treatment groups over the different time periods, while a logarithmic transformation was used to compare asymmetrically distributed quantitative variables. The significance level was set at 5%.

RESULTS

Eligible participants were recruited from September 2018 to May 2020. A total of 49 patients were allocated as follows: 24 to the group that began with PFPT and 25 to the group that began with the mindfulness protocol. Participants were evaluated at baseline, after each intervention, and 8 months after the final therapy. The sample was homogeneous in terms of baseline sociodemographic and clinical characteristics (Table 1), with no significant differences between the groups. Of the 49 patients, 38 participated in both interventions and were evaluated at all 4 time points.

SF-36 Quality of Life Questionnaire

In the mental health domain, significant differences were observed between the groups over time (p=0.001) (Figure 2, Table 2); in the group that started with PFPT, there was a significant improvement (p<0.05) in mental health scores after both interventions were performed (Time 3). In the group that started with meditation, there was a trend toward improved mental health after undergoing the mindfulness protocol (Time 2). However, when this group underwent PFPT (Time 3), there was a significant drop in mental health scores, with a trend toward

improvement during follow-up (Time 4). In the remaining seven domains of the SF-36 questionnaire, the groups varied similarly over time; the scores of both groups improved significantly, except in the emotional performance domain, which remained stable (Table 2).

Mindfulness Attention Awareness Scale

In the MAAS questionnaire, there was a trend toward improvement in both groups during the therapeutic process, and the gains were significant in follow-up (Time 4) (Table 2).

Visual Analog Scale

The VAS results were the mean of pain scores at different times, i.e., at leisure, at work, during and after sexual intercourse, urination, evacuation, and remaining in a sitting position. Both groups showed significant and progressive improvement in all post-intervention stages (Times 2 and 3), maintaining the gains in follow-up (Time 4) (Supplementary Figure S1, Supplementary Table S2.

Physical Examination and Biofeedback

Regarding the physical examination and biofeedback, the groups evolved differently in most scores. The 7 evaluated scores were PEX_0002/0006/0009/011 (number of vaginal trigger points, contraction orientation, coordination, timing, respectively) and BFB_0001/0005/0007 (initial rest, mean of sustained contraction, and final rest, respectively). The group that started with PFPT obtained significant improvement soon after the first intervention (Time 2) and maintained these gains in the following evaluations. The group that started with meditation obtained significant improvement only at Time 3, after both interventions had been completed (Figure 3, Table 2).

In the other 6 physical examination and biofeedback scores (PEX_001/003/0005/0008 - abdominal pain and contracture,

Table 1. Comparison of clinical and demographic characteristics between the groups

Characteristics	Physical therapy + meditation (n=24)	Meditation + physical therapy (n=25)	*p*-value
Age (years), mean (SD)	52.4 (8.9)	52.3 (11.3)	0.974
BMI (kg/m2), mean (SD)	26.6 (4.9)	28.1 (4.1)	0.260
Marital status, n (%):			0.387
Married	16 (66.7)	13 (52.0)	
Separated/single/widow	8 (33.3)	12 (48.0)	
Education level, n (%):			0.950
Elementary school	7 (31.8)	9 (36.0)	
High school	11 (50.0)	12 (48.0)	
Higher/graduate	4 (18.2)	4 (16.0)	
Smoker or former smoker, n (%)	5 (20.8)	5 (20.0)	0.999
Clinical diagnosis associated with pelvic pain, n (%)	19 (79.2)	22 (88.0)	0.463
Medication use, n (%)	17 (70.8)	14 (56.0)	0.435
Physical/psychological abuse or trauma, n (%)	18 (75.0)	13 (52.0)	0.170
Some complication, n (%)	9 (37.5)	11 (44.0)	0.863
Any pelvic surgery, n (%)	17 (70.8)	17 (68.0)	0.999
Physical activity >3 x a week, n (%)	7 (29.2)	6 (24.0)	0.932
Daily consumption of >3 cups of coffee, n (%)	7 (29.2)	3 (12.0)	0.171
Associated urinary loss, n (%)	22 (91.7)	20 (80.0)	0.417
Bladder pain when urinating, n (%)	14 (58.3)	19 (76.0)	0.311
Bladder-emptying difficulties, n (%)	18 (75.0)	23 (92.0)	0.138
History of recurrent urinary tract infection, n (%)	10 (43.5)	7 (30.4)	0.541
Ingestion of more than 2 L, n (%)	3 (12.5)	5 (20.0)	0.702
Emptying the bladder >11 times a day, n (%)	7 (30.4)	9 (36.0)	0.919

Student's t-test for independent samples was used for quantitative variables and Fisher's exact test or chi-square test was used for categorical variable
BMI: Body mass index; SD: Standard deviation

Table 2. Comparison of scores over time between the physical therapy + meditation and meditation + physical therapy groups

	Physical therapy + meditation				Meditation + physical therapy				*p*-value*
Scores	**Times**				**Times**				
	T1 (n=24)	**T2 (n=24)**	**T3 (n=23)**	**T4 (n=21)**	**T1 (n=25)**	**T2 (n=25)**	**T3 (n=21)**	**T4 (n=17)**	
SF-36									
MH	44 (12-84)^{A}	54 (12-100)^{AB}	72 (20- 100)^{aB}	72 (24-96)^{B}	52 (16-84)^{AB}	64 (4-88)^{A}	44 (0-96)^{bB}	60 (8-92)^{AB}	0.001
RE	33.3 (0-100)	16.7 (0-100)	33.3 (0-100)	100 (0-100)	33.3 (0-100)	66.7 (0-100)	100 (0-100)	66.7 (0-100)	0.636
SF	25 (0-100)^{A}	62.5 (0-100)^{B}	62.5 (12.5- 100)^{B}	100 (12.5-100)^{B}	37.5 (0-100)^{A}	50 (0-100)^{B}	62.5 (12.5-100)^{B}	62.5 (12.5-100)^{B}	0.724
P	41 (20-62)^{A}	41 (10-90)^{AB}	51 (10-90)^{AB}	51 (20-90)^{B}	31 (0-80)^{A}	50 (0-90)^{AB}	50 (10-100)^{AB}	51 (10-90)^{B}	0,147
RF	55 (10-95)^{A}	67.5 (20-95)^{A}	85 (20- 100)^{AB}	80 (30-100)^{B}	50 (15-90) ^{A}	60 (5-95)^{A}	75 (0-100)^{AB}	75 (10-100)^{B}	0.604
RF	12.5 (0-100)^{A}	87.5 (0-100)^{B}	100 (0- 100)^{B}	75 (0-100)^{B}	25 (0-100)^{A}	50 (0-100)^{B}	75 (0-100)^{B}	75 (0-100)^{B}	0.112
V	42.5 (0-95)^{A}	60 (0-100)^{A,B}	55 (0-100)^{B}	65 (5-90) ^{A,B}	40 (5-85) ^{A}	60 (5-85) ^{A,B}	55 (10-100)^{B}	60 (5-85)^{A,B}	0.516
GH	37 (5-92) ^{A}	61 (10-95) ^{B}	62 (20-90) ^{B}	62 (15-95)^{B}	42 (0-82)^{A}	52 (20-72) ^{B}	52 (22-72)^{B}	55 (25-92)^{B}	0.344
MAAS	52.9±17.3^{A}	58.8±16.0 ^{A,B}	59.5±18.1 ^{A,B}	60.8±16.9^{B}	57.5±19.5^{A}	62.0±17.0^{A,B}	63.1±17.4^{A,B}	64.4±17.4^{B}	0.972
Pain-VAS	6.7 (0-10)^{A}	4 (0-9.3)^{B}	3.7 (0-9.3)^{C}	0 (0-8.3)^{C}	7 (0-10)^{A}	6 (0-9.3)^{B}	1.7 (0-8)^{C}	0 (0-5.3)^{C}	0.070
PEX+BFB									
PEX_0001	23 (95.8%)^{A}	11 (45.8%)^{B}	6 (27.3%)^{C}	4 (21.1%)^{C}	23 (95.8%)^{A}	19 (79.2%)^{B}	6 (28.6%)^{C}	3 (17.6%)^{C}	0.108
PEX_0002	7 (2-13)^{A}	2 (0-7)^{aB}	1 (0-10)^{BC}	1 (0-3)^{C}	6.5 (2-10)^{A}	5.5 (2-11)^{bA}	2 (0-4)^{B}	1 (0-4)^{C}	<0.001
PEX_0003	1.5 (0-3)^{A}	4 (0-5)^{aB}	4 (0-5)^{aBC}	5 (0-5)^{C}	1 (0-5)^{A}	2 (0-5)^{bB}	3 (0-5)^{bBC}	4 (1-5)^{C}	0.002
PEX_0004	1 (0-4)	2 (0-4)	1 (0-4)	0 (0-4)	0 (0-4)	1 (0-4)	0 (0-4)	0 (0-4)	0.742
PEX_0005	1.5 (0-6)^{A}	5 (0-8)^{aB}	5.5 (0- 10^{B}	8 (0-14)^{C}	1.5 (0-8)^{A}	2 (0-8)^{bB}	4 (0-10)^{C}	6 (0-10)^{C}	<0.001
PEX_0006***	13 (59.1%)^{A}	22 (95.7%)^{B}	19 (90.5%)^{B}	18 (97.7%)^{B}	10 (43.5%)^{A}	12 (52.2%)^{A}	18 (94.7%)^{B}	16 (94.1%)^{B}	0.009
PEX_0007	3 (2-5) ^{A}	5 (3-8)^{aB}	4 (3-6)^{aB}	4 (3-8)^{B}	3 (2-5)^{A}	3 (1-6)^{bAB}	4 (2-6)^{bAB}	4 (2-11)^{B}	0.011
PEX_0008	10 (41.7%)^{A}	21 (87.5%)^{B}	19 (86.4%)^{BC}	18 (94.7%)^{C}	4 (16.7%)^{A}	9 (37.5%)^{B}	14 (70%)^{BC}	13 (76.5%)^{C}	0.245
PEX_0009	3 (12.5%)^{A}	16 (66.7%)^{aB}	16 (72.7%)^{B}	17 (89.5%)^{B}	1 (4.2%)^{A}	2 (8.3%)^{bA}	15 (71.4%)^{B}	13 (76.5%)^{B}	0.004
PEX_0010	20 (87%)	10 (55.6%)	7 (50%)	4 (23.5%)	20 (100%)**	18 (81.8%)	11 (61.1%)	3 (20%)	**
PEX_0011	4 (16.7%)^{A}	17 (77.3%)^{aB}	15 (71.4%)^{B}	15 (79%)^{B}	7 (29.2%)^{A}	10 (41.7%)^{bA}	17 (81%)^{B}	15 (88.2%)^{B}	0.001
BFB_0001	2.4 (0-33.6)^{A}	6.0 (0-16.4)^{aB}	4.5 (0-19.9)^{AB}	5.3 (1.5-20)^{B}	0 (0-9.1)^{A}	2.2 (0-19.6)^{bA}	5.8 (0-19.7)^{B}	5.9 (1.6-24.4)^{B}	0.002
BFB_0002	0.7 (0-1.6)	0.8 (0.2-1.9)^{a}	0.7 (0.3-1.8)	0.8 (0-1.6)	0 (0-1.7)^{A}	0.5 (0-1.4)^{bA}	1.0 (0-1.8)^{B}	0.9 (0.3-1.6)^{B}	0.004
BFB_0003	0.8 (0-2.3)^{A}	1.3 (0-3)^{B}	1.3 (0-2.6)^{B}	1.4 (0-1.9)^{B}	0 (0-1.9)^{A}	0.8 (0-2.5)^{B}	1.2 (0-2.2)^{B}	1.2 (0.7-1.9)^{B}	0.163
BFB_0004	16.5 (0-123.9)^{A}	42.1 (0-171.6)^{aB}	46.4 (0-108.3)^{B}	44.9 (7.5-149.2)^{B}	0 (0-90.2)^{A}	18.1 (0-174.7)^{bB}	28.0 (0- 252.8)^{C}	31.4 (4.4-118.8)^{D}	0.035
BFB_0005	7.4 (0-57.6)^{A}	20.1 (0-67.7)^{aB}	26.3 (0-103.4)^{B}	23.2 (3.6-74.4)^{B}	0 (0-60.1)^{A}	11.1 (0-100.7)^{bA}	13.6 (0-135.7)^{B}	22.5 (2.8-62.6)^{B}	0.031
BFB_0006****	33.4 (17.7-87.1)^{A}	24.9 (13.3-43.8)^{aB}	26.2 (12.6-47.3)^{A}	26.9 (17-61.8)^{aA}	29.7 (19.3-56.6)^{A}	34.5 (20.5-67.5)^{bA}	31.3 (13.8-83.5)^{AB}	22.7 (12.1-38.8)^{bB}	0.001
BFB_0007	2.1 (0-13.2)^{A}	5.7 (0-15.6)^{aB}	5.8 (0-11.8)^{B}	5.7 (1.9-10.1)^{B}	0 (0-12.1)^{A}	1.8 (0-14.2)^{bA}	5.0 (0-20.6)^{B}	4 (1.5-29.5)^{B}	0.001

Different lowercase letters represent differences between groups within each time, different uppercase letters show differences between times within each group.
Times: T1: Pretreatment; T2: First assessment; T3: After the sequence of treatments; T4: Late comparison at follow-up; *: The *p*-value <0.05 of the interaction when indicates that the groups varied in different ways throughout the assessment moments; **: Assessment was impossible due to the lack of negative participants at baseline in the meditation + physical therapy group; ***: Head position; ****: Only patients who could perform a contraction with a head command were included; BFB: Biofeedback; GH: General health; MAAS: Mindfulness attention awareness scale; MH: Mental health; P: Pain; PEX: Physical examination; RE: Role-emotional; RP: Role-physical; SF: Social functioning; V: Vitality; VAS: Visual analog scale; PEX_0001: Number of women with abdominal pain and contracture; PEX_0002: Mean number of myofascial trigger points in the vagina; PEX_0003: Mean of muscle power according to the Oxford scale; PEX_004: Grades of pelvic organ prolapse; PEX_0005: Mean of sustained contraction in seconds; PEX_0006: Number of women with contraction orientation; PEX_0007: Number of repetitions of one-second fast contractions in 11 seconds (with a 2-second rest between them); PEX_0008: Number of women showing contraction with puborectal musculature elevation; PEX_0009: Number of women with coordination; PEX_0010: Number of women who used accessory muscles; PEX_0011: Number of women with timing (pre-contraction); BFB_0001: Mean of initial rest in seconds; BFB_0002: Mean of fast contraction ramp-up in seconds; BFB_0003: Mean of contraction ramp-down in seconds; BFB_0004: Mean of maximum voluntary contraction in seconds; BFB_0005: Mean of sustained contraction in seconds; BFB_0006: Mean variability of the amplitude of sustained contraction (%); BFB_007: Mean of final rest in seconds

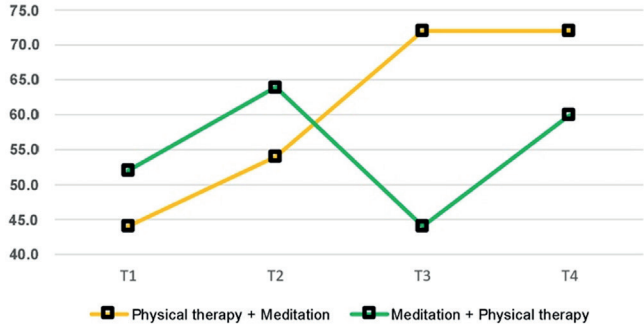

Figure 2. Mental health results (SF-36) over time in both treatment groups
*: p<0.05; T1: Pretreatment; T2: First assessment; T3: Assessment after undergoing both treatment interventions; T4: Late comparison at follow-up

power, endurance, and pubo-vaginal/rectal elevation, respectively; BFB_003/004 - fast contraction ramp-down and maximal voluntary contraction, respectively), there was a significant improvement (p<0.005) after the first intervention (Time 2) in both groups, followed by maintained gains or significant progressive improvement in the other evaluations (Figure 4, Table 2).

In the fast contraction score (PEX_0007), the group that started with PFPT had significant improvement after the first intervention (Time 2) and maintained it throughout follow-up. The group that started with meditation, despite a trend toward improvement, only showed significant improvement in follow-up (Time 4) (Table 2).

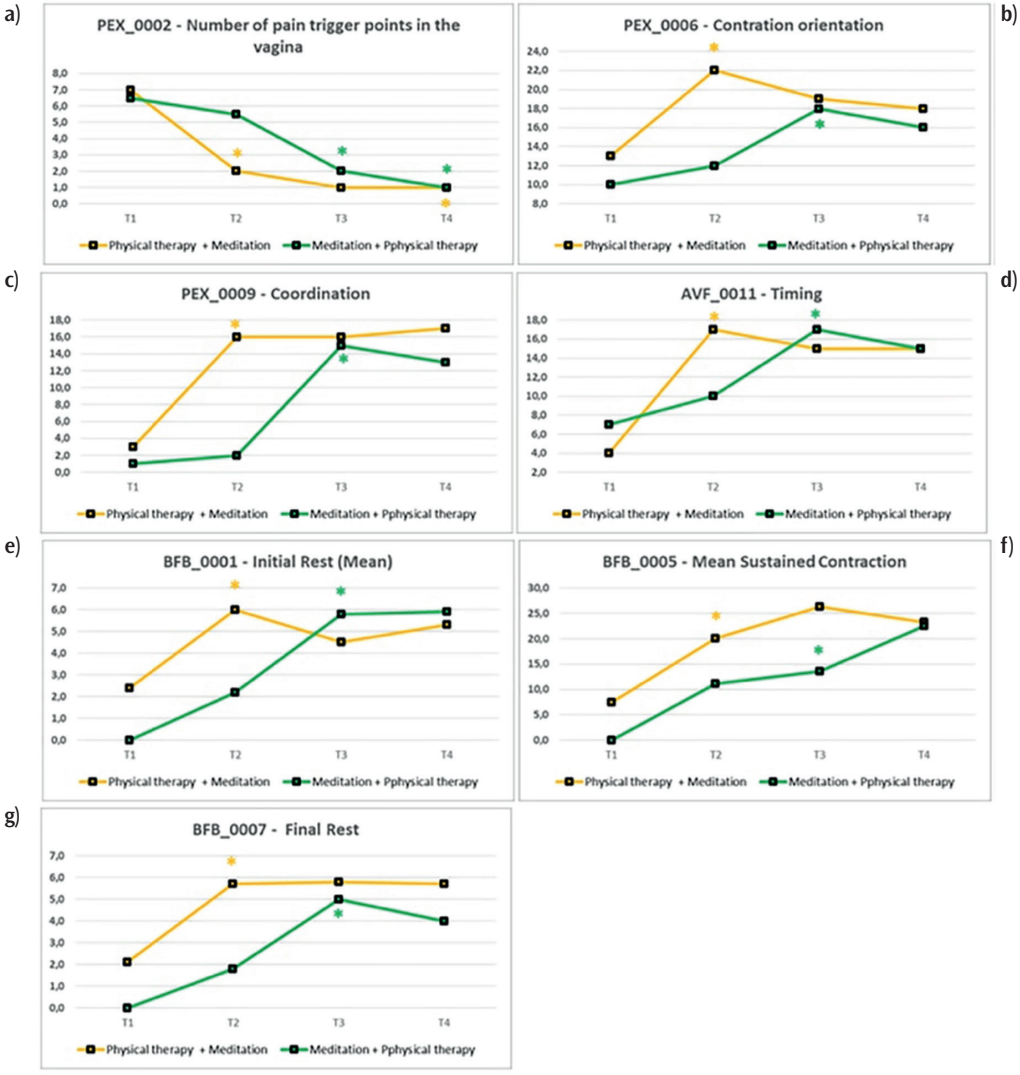

Figure 3. Physical examination and biofeedback scores PEX_0002/0006/0009/0011 and BFB_0001/0005/0007. a) PEX_0002 - Mean number of myofascial trigger points in the vagina; b) PEX_0006 - Number of women with contraction orientation; c) PEX_0009 -Number of women with coordination; d) PEX_0011 - Number of women with timing (pre-contraction); e) BFB_001 - Mean of initial rest in seconds; f) BFB_005 -Mean of sustained contraction in seconds; g) BFB_007 - Mean of final rest in seconds.
*: P<0.05, the group starting with pelvic floor physical therapy obtained significant gains earlier (T2) than the group starting with mindfulness, which obtained significant gains only at T3

In the fast contraction ramp-up score (BFB_0002), the group that started with PFPT did not change over time, while the group that started with the meditation protocol showed significant improvement after the second intervention (Table 2).

In mean variability of the amplitude of sustained contraction (BFB_0006), the group that started with pelvic physical therapy obtained a significant improvement after the first intervention (Time 2), although at the other time points it returned to its initial state. The group that started with the meditation protocol obtained significant improvement only during follow-up (Time 4) (Table 2).

DISCUSSION

The present randomized controlled trial evaluated the effectiveness of a multidisciplinary therapy comprising PFPT and a mindfulness protocol in women with CPP. The participants were evaluated at 4 time points, and the effectiveness of each therapy was observed separately and as the sum of both interventions. A limitation of this study is that it represents the experience of a single center, which limits the generalization of the results to populations with different characteristics.

Some results suggest that there is a difference between starting treatment with PFPT and meditation, while others suggest that there is no difference. One score indicating that it is ideal to start with PFPT was mental health (SF-36), which showed progressive improvement during the therapeutic process, while starting with the meditation protocol had a negative effect on mental health, since scores decreased during the second intervention. This could be related to the fact that patients received psycho-emotional support from the group meetings provided by the cognitive

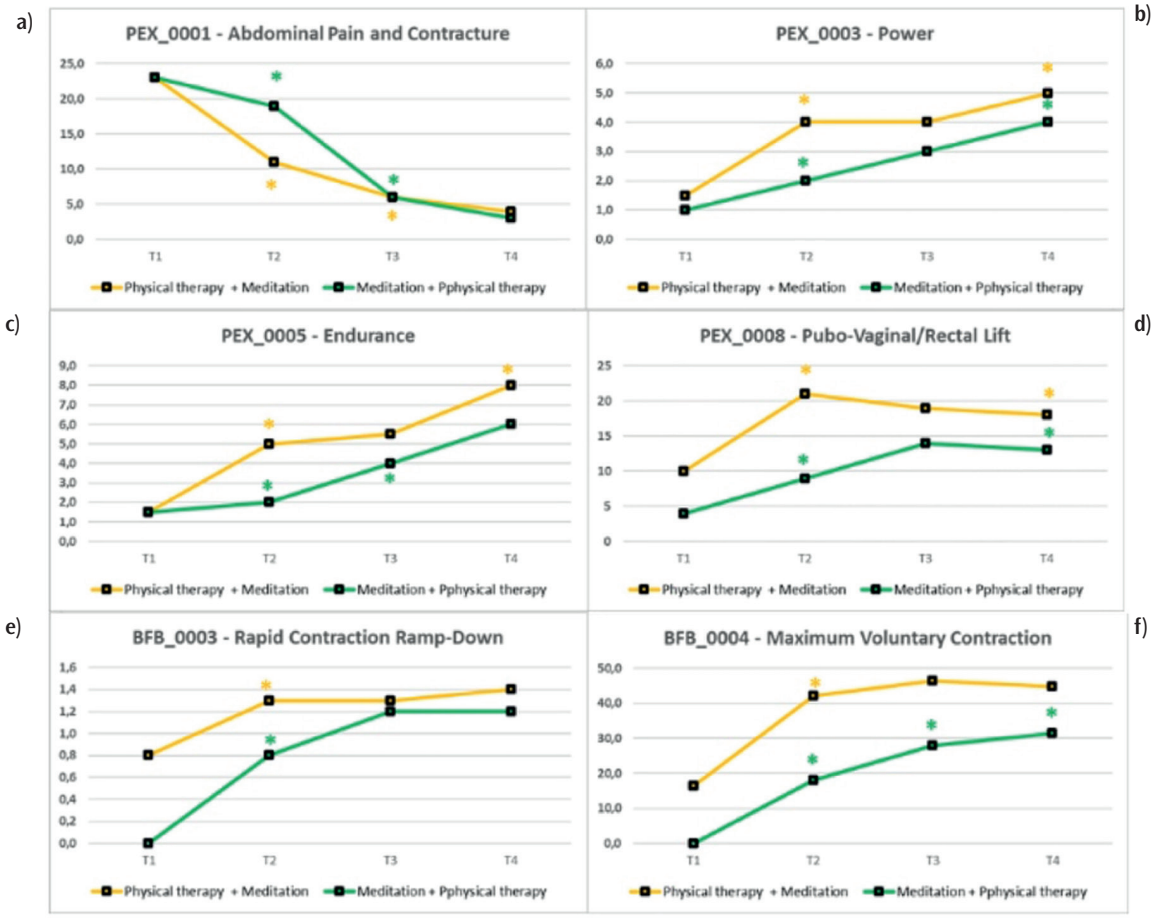

Figure 4. Physical examination and biofeedback scores PEX_0001/0003/0005/0008 and BFB_0003/0004. a) PEX_0001 - Number of women with abdominal pain and contracture; b) PEX_0003 - Mean of muscle power according to the Oxford scale; c) PEX_0005 – Mean of sustained contraction in seconds; d) PEX_0008 -Number of women showing contraction with puborectal musculature elevation; e) BFB_0003 -Mean of contraction ramp-down in seconds; f) BFB_0004 - Mean of maximum voluntary contraction.
*: $P<0.05$, both groups obtained significant gains immediately after the first intervention (T2)

intervention, which was followed with real contact with the pain site in PFPT, temporarily exacerbating the sensation of pain.

When PFPT was the first intervention, significantly faster improvement occurred in the physical examination domains number of trigger points (PEX_0002), contraction orientation (PEX_0006), fast contraction (PEX_ 0007), coordination (PEX_0009), and pre-contraction (PEX_0011), as well as in the biofeedback results initial rest (BFB_0001), mean sustained contraction (BFB_0005) and final rest (BFB_0007) (Figure 4, Table 2).

There is consensus in the literature that PFPT is an effective treatment for myofascial pain, which is a cause or consequence of CPP in most women with this condition. This is especially the case when it includes correct orientation of muscle contraction and relaxation, release of pain trigger points, electrical stimulation, negative electromyographic biofeedback, the use of heat, and kinesiotherapy.[6,9,11,19]

When the mindfulness protocol occurred first, the gains were significantly greater or more rapidly acquired for sustained contraction - endurance (PEX_005), fast contraction ramp-up (BFB_0002), and mean sustained contraction (BFB_0004), suggesting that mindfulness training can prepare patients for physical learning (Table 2).

Mindfulness focuses on teaching two skills: Self-regulation of attention, which leads to an awareness of the present moment, and an orientation towards one's own experiences, accepting them without judgment. These elements enable mindfulness practitioners to be less reactive and to free themselves from maladaptive patterns of thought and behavior triggered by the experience of pain.[5,12,13,20]

Mindfulness-related neural mechanisms of pain relief have been explained by neuroimaging studies. Zeidan et al.[21] observed that mindfulness induced greater activation of the bilateral orbitofrontal cortex and the rostral anterior cingulate cortex, in addition to greater thalamic deactivation. Orbitofrontal cortex activation is associated with increased positive mood and altered contextualization of sensory events, while rostral anterior cingulate cortex acts on affective pain modulation. Both reduce ascending nociceptive inputs (thalamic deactivation) to somatosensory cortical regions. Such cognitive control modulates the habitual patterns of catastrophizing, fear, anxiety, and avoidance associated with the subjective experience of pain.

However, other scores, including abdominal pain and contracture (PEX_0001), contraction with puborectal musculature elevation (PEX_0008), contraction ramp-down (BFB_0003), as well as the social functioning, physical performance, and general health domains of the SF-36 questionnaire and the VAS did not differ according to initial therapy type, since the groups had a similar evolution during the treatment process and significant improvement occurred soon after the first intervention (PFPT or mindfulness protocol).

Other scores showed that the sum of the interventions was effective: Abdominal pain and contracture (PEX_0001), the VAS scales for both groups, and the contraction support-endurance (PEX_005) and maximum voluntary contraction (BFB_004), for the group that started with the mindfulness protocol (Table 2).

These analyses suggest that simultaneous performance of both therapies would optimize gains in quality of life, pain management, and pelvic floor health of women with CPP. This may be due to the fact that these therapies focus on different dimensions of CPP. While PFPT acts on the myofascial component of the pain stimulus, mindfulness acts on minimizing the central amplification of pain.[22]

The literature corroborates our results, showing the need for 3 levels of CPP treatment due to its multifactorial and multidimensional nature: Organic (damage/disturbance), personal (disability level), and social (limited participation due to behavioral consequences), indicating that a broader approach involving interdisciplinary care is required. However, no previous study has described a PFPT protocol associated with a mindfulness protocol.[6,9,23,24]

In addition, of the 28 scores included in the SF-36, MAAS, VAS, physical examination and biofeedback questionnaires, gains were evidenced in 22 during follow up in the group that started with PFPT [all except: "Is there pelvic organ prolapse?" (AVF_004), "use of accessory muscles" (AVF_010), "contraction ascent ramp" (BFB_002), "contraction orientation" (BFB_006), "emotional performance" and "vitality" (SF-36)]. In the group that started with meditation, gains were evidenced in 23 [all except: "mental health", "emotional performance", "vitality", "is there pelvic organ prolapse?" (AVF_004), "use of accessory muscles" (AVF_010)] (Table 2).

These results differ from most patients who receive traditional, unimodal therapy for CPP and continue to seek a medical cure for their pain. It appears that the patients in the present study acquired self-control and learned to face their pain in a more rational and functional way.[23,25]

CONCLUSION

In conclusion, our results suggest that multidisciplinary treatment consisting of PFPT and mindfulness training is safe and effective for women with CPP. As a study limitation and a suggestion for future research, larger prospective multicenter studies should perform both interventions simultaneously to optimize the results.

ETHICS

Ethics Committee Approval: All processes in the present study were conducted in accordance with the ethical standards of our institution and the 1975 Declaration of Helsinki (2008 revision). The protocol of this study was approved by Hospital de Clínicas (ethics committee approval 58855116.6.0000.0096; DATA and the Brazilian Registry of Clinical Trials (ID13375).

Informed Consent: Written informed consent was obtained from all participants prior to enrollment.

FOOTNOTES

Contributions

Concept: C.C.B.; Data Collection or Processing: C.C.B., C.M., G.A., R.R., R.D.F.; Analysis or Interpretation: C.C.B., T.M.; Writing: C.C.B., C.M.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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Information: All relevant data are within the paper. This paper includes results of the doctoral dissertation submitted by the principal investigator to Universidade Federal do Paraná (UFPR) in 2022, which is available for download from the UFPR Institutional Digital Repository (https://hdl.handle.net/1884/81117).

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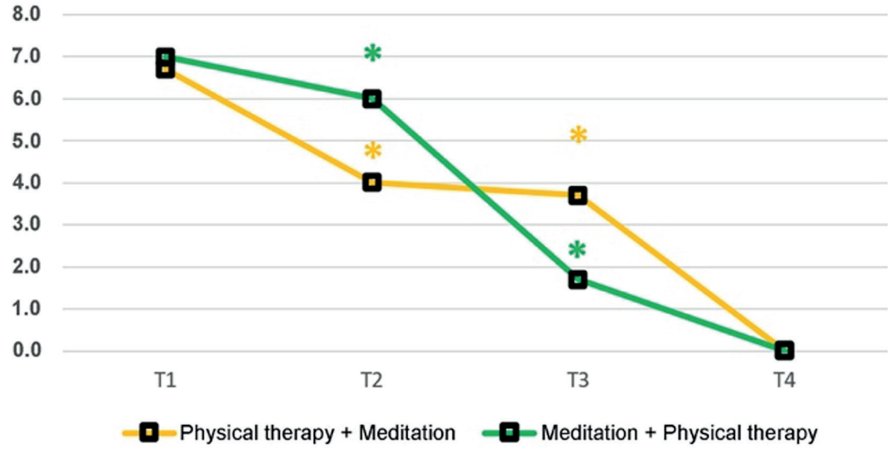
Supplementary Table S1. Content of the 8-session mindfulness program

1st session	What is mindfulness? Exiting autopilot
2nd session	Breath mindfulness
3rd session	Mindfulness in daily life
4th session	Extending mindfulness skills to challenging situations
5th session	Mindfulness of mind and thoughts
6th session	Day of silence
7th session	Mindfulness and compassion
8th session	Mindfulness for life

Supplementary Table S2. Pelvic floor physical therapy program

1st	2nd	3rd	4th	5th	6th	7th	8th
Reception and basic orientation	Electrotherapy 3 Hz 15 min	Electrotherapy 3 Hz/250 Ms 15 min					
Anatomical orientation	Electrotherapy <10 Hz	Electrotherapy -50 Hz/250 Ms watching voluntary contraction					
Orientation about finding the perineum	Reorientation		Awareness of contraction				
Orientation about feeling the perineum	Reorientation		Internal and external self-touch	Internal and external self-massage			
Orientation about contracting the perineum	Biofeedback	Biofeedback as a participant	Negative biofeedback				
Orientation about the use of heat*	Self-perception		Perineal massage		Perineal massage with contraction		
Forward	Orientation about contraction and relaxation	Orientation about daily exercises					



Supplementary Figure S1. Mean of pelvic pain scores according to the visual analog scale in both treatment groups

*: $P<0.05$, both groups obtained significant gains immediately after the first intervention (T2)