Efficacy of manual therapy and pelvic floor exercises for pain reduction in primary dysmenorrhea: A prospective observational study

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A B S T R A C T

Background: Primary dysmenorrhea represents one of the most common causes of pelvic and low back pain. Pharmacological treatment can present some side effects, and non-pharmacological treatments should be considered to improve the symptoms of primary dysmenorrhea. The aim of this study was to evaluate the efficacy of manual therapy (MT), pelvic floor exercises (PFE), and their combination (MT + PFE) to improve clinical outcomes and pain sensitivity in women with primary dysmenorrhea.

Methods: A prospective observational study was conducted. Thirty females (age 25.0 ± 6.1 y) with history of primary dysmenorrhea participated to 8 sessions of 60 min of either MT, PFE or MT + PFE, twice per week. They participated to the different treatments according to the different services offered by the school of physiotherapy. A 0–10 numeric rating scale (NRS) was administered to assess subjective pain, while short-form 36 (SF-36) was used to evaluate quality of life. The pressure pain threshold (PPT) was assessed with a portable algometer on different pelvic and lumbar areas.

Results: Independently from the treatment, significant improvements were reported for general pain NRS ($p < 0.001$; $p\eta^2 = 0.511$), as well as most the domains of the SF-36, although the general health domain did not reach statistical significance ($p = 0.613$; $p\eta^2 = 0.010$). PPT revealed a general improvement in all tested body areas, although on the quadratus lumborum, the PFE treatment did not induce a significant improvement compared to the MT and MT + PFE protocols ($p = 0.039$).

Conclusions: These findings highlight the importance of proposing physiotherapy treatments to females with primary dysmenorrhea to improve symptoms, with manual therapy combined with active pelvic floor exercise providing the best outcomes including an improvement of lumbar pain thresholds.

1. Introduction

Among menstrual disorders, dysmenorrhea is characterized by the presence of painful cramps of uterine origin that occur during menstruation (López-Liria et al., 2021). Its prevalence can range from 16 to 91% of reproductive-age women and can severely affect the quality of life (Karanth and Liya, 2018). Indeed, as one of the most common causes of pelvic pain, it often results in reduced working capacity, short-term absenteeism, and overal poor quality of life, among young and adult women (Harel, 2006; Petraglia et al., 2017). Primary dysmenorrhea is defined as menstrual pain associated with normal ovulatory cycles, without pelvic pathology, and a clear physiological aetiology, and it is most common in adolescents and young adults (Harel, 2006). The pathophysiology of primary dysmenorrhea is due to increased and/or abnormal uterine activity because of increased production and release of prostaglandins (Zahradnik and Breckwoldt, 1984).

Among the different treatment options, pharmacological therapy is often suggested, in particular prostaglandin (PG) inhibitors, as non-steroidal anti-inflammatory drugs (NSAIDs), and hormonal drugs such as contraceptives (Zahradnik et al., 2010). Nevertheless, despite its efficacy, pharmacological treatments might present some side effects, and the prolonged use of NSAIDs and contraceptives might promote several health problems (Zahradnik et al., 2010).

Alternative treatments options, such as non-pharmacological and

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non-invasive interventions, have been proposed to improve the symptoms of primary dysmenorrhea, such as acupuncture and acupressure, biofeedback, heat treatments, transcutaneous electrical nerve stimulation (TENS), exercises and relaxation techniques (Fernández-Martínez et al., 2019; Kannan and Claydon, 2014). The study of physiotherapeutic techniques has been strongly encouraged, as they might be proposed to those women who are not eligible for other pharmacological or invasive treatments and could represent an alternative therapeutic approach with minimal or null side effects (Fernández-Martínez et al., 2019; Kannan and Claydon, 2014).

Since pain represents the primary symptom of dysmenorrhea, physical therapy interventions should aim to reduce pain sensation and improve the overall quality of life. Previous findings found a significant reduction in pain severity with non-pharmacological interventions such as acupuncture and acupressure, heat therapy, TENS, and yoga (Kannan and Claydon, 2014). Manual therapy has been suggested as an alternative treatment option to reduce primary dysmenorrhea symptoms, presenting some significant effects compared to ibuprofen (Barcikowska et al., 2022), and despite more high-quality research is recommended, it might represent a possible adjunct therapy in the relief of pain in these individuals (Abaraogu et al., 2017). In addition, exercise for about 45–60 min each time, three times per week or more, regardless of intensity, may provide a clinically significant reduction in menstrual pain intensity (Armour et al., 2019).

Manual therapy and active exercise, therefore, represent two possible non-pharmacological treatment options that might be performed without the need for specific equipment (as for heat therapy or TENS), acting on different pathophysiological mechanisms that might be associated with menstrual pain, such as mechanoreceptors sensitization and overall health status improvement (Barassi et al., 2021; Carroquino-Garcia et al., 2019). It might be speculated that since the two approaches might act on some different pathways for pain reduction in primary dysmenorrhea, their combination might provide a better benefit than the single treatment protocol.

In most of the above-mentioned studies, pain reduction was assessed by the administration of a numerical pain rating scale. Despite numerical rating scales being widely used and well-validated also in primary dysmenorrhea, it might be complicated to provide a more specific representation of pain in different body areas (Chen et al., 2015; Deŕman et al., 2004). Pressure pain threshold (PPT) represents an objective measure of mechanical pain sensitivity in different body areas (Castien et al., 2021; Park et al., 2011), which might be heightened in young female adults with moderate-to-severe menstrual pain (Slater et al., 2015). Such a technique can also be used to assess the efficacy of different therapeutic protocols on pain sensitivity in other diseases, as well as in primary dysmenorrhea (Machado et al., 2019). As such, the aim of this randomized study was to compare the effect of two different non-pharmacological treatments (manual therapy and active exercise focused on pelvic floor muscles), and their combination, of subjective rating of pain, PPT, and quality of life, in young females with primary dysmenorrhea diagnosed by a gynecologist within 2 years of menarche (Ferries-Rowe et al., 2020).

2. Materials and methods

This prospective observational study included three-arms of treatment and was performed in a sample of women with primary dysmenorrhea who were recruited among the people attending the rehabilitation service of the [omitted for review only]. To be included in this study participants had to be diagnosed with primary dysmenorrhea (Ferries-Rowe et al., 2020), aged between 20 and 45 years, being nulliparous, and report the presence of pelvic pain and low back pain during menstruation. Participants were excluded if they regularly used contraceptives, if they reported any pelvic disease or any medical condition which might have influenced the results, if they presented a psychiatric condition or cognitive deficit, if they reported a history of fractures or surgery at abdominal, pelvic and spine levels, or if they were pregnant during the study. We asked the participant to limit the consumption of medication for pain relief at a maximum of one dose each menstruation period. All the participants gave their written informed consent, the study was conducted according to the principles of the Declaration of Helsinki, and the protocol was approved by the ethical committee of the [omitted for review only].

Participants were selected among those participating to different treatment protocols offered by the university hospital rehabilitation services: manual therapy (MT), pelvic floor exercises (PFE), or combined treatments (MT + PFE). Before starting the treatments, all the participants were evaluated during the first 3 days of the menstruation phase, which is considered to be the most painful (Iacovides et al., 2015). All the assessments were repeated at the end of the treatments, during the first 3 days of the following menstruation phase.

2.1. Evaluation methods

The evaluation consisted of an anamnestic questionnaire, including a subjective reporting of the symptoms, the administration of a numerical rating scale (NRS) to assess pelvic pain, lumbar pain, and general pain from 0 (no pain) to 10 (severe pain) (Bourdel et al., 2015; Karcioglu et al., 2018), the Italian version of the SF-36 to investigate different aspects of the quality of life from 0 to 100 (physical functioning, PF; role-physical, RP; role-emotional, RE; bodily pain, BP; general health, GH; vitality, VT; social functioning, SF; mental health, MH) (Apolone and Mosconi, 1998), and the assessment of the pressure pain threshold (PPT). The SF-36 is one of the most used instruments for measuring the general state of health. It is often used in studies on gynecological problems such as endometriosis. The typical structure of SF-36 hypothesizes that PF, RP, BP and GH are subcategories of the physical component, while RE, VT, MH and SF are subcategories of the mental component. The score can be calculated for each sub-category or a summary score can be calculated for mental or physical dimensions. For each of the sub-categories or for each of the components, a higher score indicates a better state of health for each dimension. Scores are generally transformed to a range from 0 to 100 for the 8 subscales (Stull et al., 2014; Yonglitthipagon et al., 2017).

To investigate musculoskeletal pain sensitivity to mechanical stimuli, PPT was assessed with an algometer (Somedic Sales, Hörby, Sweden) on different body areas (Fig. 1), representing typical painful areas in women with pelvic pain according to previous literature (Alfonsin et al., 2019). The algometer was placed with the probe (circular 1 cm^2) against the muscle belly, according to standard procedures, and pressure was increased at a rate of 30 kPa/s (Deodato et al., 2022a, 2022b). Participants were instructed to press a button as soon as they perceived a painful sensation on the tested body area and the pressure value was automatically saved in the dedicated software. Before starting the muscle evaluation, the first trial was applied on the wrists of each subject to educate with the algometer assessment. The following body areas were investigated: gluteus maximus (m.GMa), proximally and laterally respect the sacrum and inferior to the posterior inferior iliac spine; gluteus medium (m.GMe), medially and inferior to the iliac spine; iliopsoas (m.IP), 3-cm medially and superior to the anterior superior iliac spine, on the imaginary line connecting with navel; multifidus (m.MF), distally between the sacrum and L5; paravertebral (m.PV), laterally to the L3 transverse process; quadratus lumborum (m.QL), proximal to the L1 transverse process; tensor fascia latae (m.TFL), distally on the muscle belly inferior to the greater trochanter; tibialis anterior (m.TA), proximal to its insertion on the tibia. The m.TA was used as a reference point that should be affected by the symptoms or by the treatments. Three measurements were performed bilaterally for each body area, alternating the side of the body and with 30-s of rest between each assessment (at least 2 min between each assessment on the same body area). The mean value was calculated and considered in the final analysis.

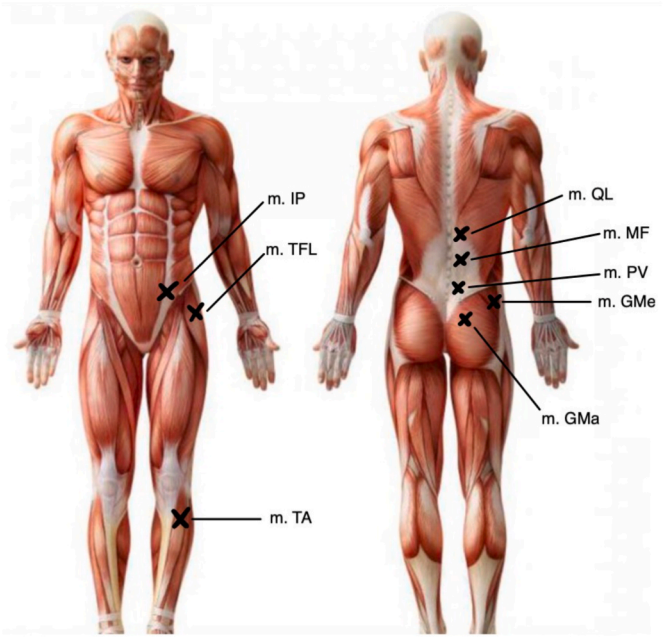

Fig. 1. Body map scheme representing the points where the algometer was applied to detect the pressure pain threshold (PPT). m.GMa: gluteus maximus, m.GMe: gluteus medium, m.IP: iliopsoas, m.MF: multifidus, m.PV: paravertebralis, m.QL: quadratus lumborum, m.TFL: tensor fascia latae, m.TA: tibialis anterior.

2.2. Interventions

All the participants were assessed before and after 8 individual sessions lasting 60 min each, performed twice per week, according to the rehabilitation service protocol. The same volume of treatment (8 h) was performed to all the subjects.

The MT group received a treatment protocol that included different techniques to improve muscle control, release soft tissues, and reduce pain (Barcikowska et al., 2022). The first technique was represented by diaphragm mobilization (Jafari et al., 2017; Rocha et al., 2015). Next, normalization of the tone of the pelvic floor muscles was achieved by myofascial release on the internal side of the ischial tuberosities (Barcikowska et al., 2022). Then post-isometric release exercise and tender point therapy were performed according to previous literature on several muscles, such as tensor fasciae latae, piriformis muscle and lumbar paravertebralis (Aziz et al., 2021; García-Peñalver et al., 2020; McNamara, 2000; Newham, 1992).

The PFE group performed different exercises with a focus on the pelvic floor. Participants were asked to void the bladder before each session (both for the PFE and MT + PFE groups). The first part of the protocol included exercises to improve proprioception and control of the pelvic floor muscles; particular attention was given to teaching to control the pelvic floor muscles without contracting other muscles such as the glutei, abductors, and abdominal muscles. Pelvic floor exercises were then included, starting from the modified gynaecological position to the standing position. Other exercises have been implemented to improve the control of the body also during dynamic tasks. Exercises to improve respiratory muscles control were also included. All the exercises were also modulated to improve phasic muscles (rapid contractions with resting phases) and tonic muscles (slow and maintained contractions).).

The MT + PFE group received both treatments by proposing the MT protocol for half of the session, and by proposing the exercises on the pelvic floor muscles during the other half.

2.3. Statistical analyses

All statistical analyses were performed with SPSS v.23 (IBM inc.). SF-36 subdomains' scores were transformed into a 0–100 score as previously described (Stull et al., 2014; Yonglitthipagon et al., 2017). All the outcomes were reported on the database by a researcher (MM) who was blinded to the participant's allocation in the different intervention groups. Another researcher (ABS) performed the statistical analysis. Shapiro-Wilk test for normality of distribution was performed. Data are reported as the medians and 25th-75th percentile, or counts and proportions (%) as appropriate. A mixed-factors ANOVA was performed to test within factor (2 x time, pre- and post-treatment) and between factor (3 x groups: MT, PFE and MT + PFE). For the PPT measurements, another within factor (2 x side, left and right) was included. In case of significant main effects, Sidak's post-hoc comparisons were performed. Partial eta-squared ($p\eta^2$) was used for effect size. Significance was set at $p < 0.05$.

3. Results

A total of 30 females (age 25.0 ± 6.1 y, 54 ± 5 kg, 1.66 ± 6.0 m) with primary dysmenorrhea were included in the study and all of them completed the study protocol. Age of menarche was 12 ± 2 y and participants reported to suffer from primary dysmenorrhea from 8 ± 4 y. No significant differences in demographics were present between the three groups (age $p = 0.127$, body mass $p = 0.225$, body height $p = 0.375$, age at menarche $p = 0.477$, history of dysmenorrhea $p = 0.761$).

3.1. NRS

According to the subjective rating of pain, all the treatment protocols were found to improve pain perception in general ($p < 0.001$; $p\eta^2 = 0.511$), in the pelvic area ($p < 0.001$; $p\eta^2 = 0.611$) as well as in the lumbar area ($p < 0.001$; $p\eta^2 = 0.771$). No group difference was reported, as well none of the protocols was found to be significantly more effective in reducing pain. Indeed, independently from the treatment, pelvic pain improved by 3.5 (95% CI: 2.4–4.6) points ($p < 0.001$), lumbar pain by 3.7 (95% CI: 2.9–4.5) points ($p < 0.001$), and general pain by 3.0 (95% CI: 1.9–4.2) points ($p < 0.001$) (Table 1). Results are reported in Fig. 2.

3.2. PPT

According to the assessed PPT in the different body areas, a significant improvement was reported for all protocols in the m.GMa ($p < 0.001$; $p\eta^2 = 0.451$), m.GMe ($p = 0.011$; $p\eta^2 = 0.214$), m.IP ($p = 0.001$; $p\eta^2 = 0.362$), m.MF ($p < 0.001$; $p\eta^2 = 0.508$), m.PV ($p = 0.001$; $p\eta^2 = 0.334$), m.QL ($p = 0.002$; $p\eta^2 = 0.308$), and m.TFL ($p = 0.028$; $p\eta^2 = 0.166$). In particular, the post-hoc analysis suggested that in the m.QL the PFE treatment did not induce a significant improvement compared to the MT and MT + PFE protocols ($p = 0.039$) (Table 1). Results are reported in Fig. 3.

3.3. SF-36

The different domains of the SF-36 were considered (Table 2). Significant improvements were reported for all treatments without group differences in the PF component ($p < 0.001$; $p\eta^2 = 0.494$), RP component ($p < 0.001$; $p\eta^2 = 0.668$), RE component ($p < 0.001$; $p\eta^2 = 0.430$), BP component ($p < 0.001$; $p\eta^2 = 0.476$), VT component ($p < 0.001$; $p\eta^2 = 0.430$), SF component ($p < 0.001$; $p\eta^2 = 0.553$), and MH component ($p < 0.001$; $p\eta^2 = 0.477$). However, no significant time effect was reported in the GH component ($p = 0.613$; $p\eta^2 = 0.010$).

Table 1
NRS and pain pressure threshold (PPT) of the included sample (n = 30).

	MT (n = 10)	PFE (n = 10)	MT + PFE (n = 10)
NRS, score			
Pelvic pain			
pre	7.7 ± 1.6*	7.3 ± 1.4*	7.6 ± 1.4*
post	4.3 ± 2.7*	4.2 ± 2.8*	3.5 ± 2.4*
Lumbar pain			
pre	5.0 ± 2.9*	5.1 ± 1.7*	4.4 ± 2.4*
post	1.6 ± 2.3*	0.6 ± 0.8*	1.3 ± 1.6*
General pain			
pre	6.1 ± 2.8*	6.5 ± 1.6*	5.7 ± 1.9*
post	2.7 ± 2.1*	3.4 ± 2.7*	3.1 ± 2.4*
PPT, kPa			
m.GMa			
pre	418.0 (329.8–506.1)*	426.6 (338.4–514.8)	460.3 (372.2–548.5)*
post	652.2 (509.7–794.6)*	507.0 (364.5–649.5)	669.2 (526.7–811.6)*
m.GMe			
pre	360.5 (294.6–426.4)	332.1 (266.2–398.1)	369.4 (303.5–435.3)*
post	472.1 (360.3–583.8)	378.9 (267.2–490.6)	457.2 (345.5–569.0)*
m.IP			
pre	184.1 (131.9–236.3)*	194.2 (142.1–246.4)	191.6 (139.4–243.7)*
post	282.6 (217.0–348.1)*	242.5 (176.9–308.1)	270.5 (204.9–336.1)*
m.MF			
pre	430.7 (328.9–532.5)*	426.3 (324.5–528.1)	444.6 (342.8–546.4)*
post	669.3 (530.9–807.8)*,#	491.5 (353.0–629.9)#	727.3 (588.9–865.8)*,#
m.PV			
pre	421.4 (329.4–513.4)*	388.4 (296.4–480.4)	417.7 (325.7–509.7)*
post	599.1 (463.8–734.4)*	413.3 (278.0–548.6)	575.2 (439.9–710.5)*
m.QL			
pre	322.7 (237.1–408.4)*	347.7 (262.1–433.3)	386.2 (300.6–471.8)*
post	504.2 (385.9–622.4)*	346.4 (228.1–464.6)	494.2 (375.9–612.4)*
m.TFL			
pre	402.3 (318.3–486.2)	346.5 (262.5–430.5)	433.3 (349.3–517.2)
post	526.9 (401.4–652.4)	355.2 (229.7–480.6)	509.8 (384.4–635.3)
m.TA			
pre	510.2 (366.1–654.3)	419.4 (275.3–563.2)	494.1 (349.9–638.2)
post	493.5 (260.5–626.5)	402.4 (269.4–535.5)	561.8 (428.8–694.7)

Notes: Numeric rating score (NRS) from 0 (no pain) to 10 (extreme pain). Pressure pain threshold (PPT, kPa) of different body areas (mean value between the two sides). m.GMa: gluteus maximus, m.GMe: gluteus medium, m.IP: iliopsoas, m.MF: multifidus, m.PV: paravertebralis, m.QL: quadratus lumborum, m.TFL: tensor fascia latae, m.TA: tibialis anterior. MT: manual therapy, PFE: pelvic floor exercises, MT + PFE: combined. *p < 0.05 for within-group significance (time), #p < 0.05 for between-group significance (treatment).

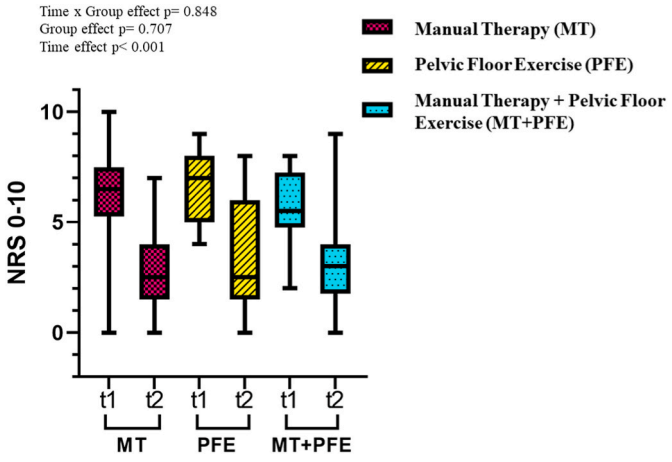

Fig. 2. Boxplots representing the difference in the general pain NRS (0–10) in the manual therapy (n = 10; MT, pink), pelvic floor exercises (n = 10; PFE, yellow) and combined protocol (n = 10; MT + PFE, light blue) groups; pre (t1) and post (t2) refer to the values before and after the treatment. Overall significant time effect ($F_{1,27} = 28{,}263$; $p < 0.001$; $p\eta^2 = 0.511$). (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

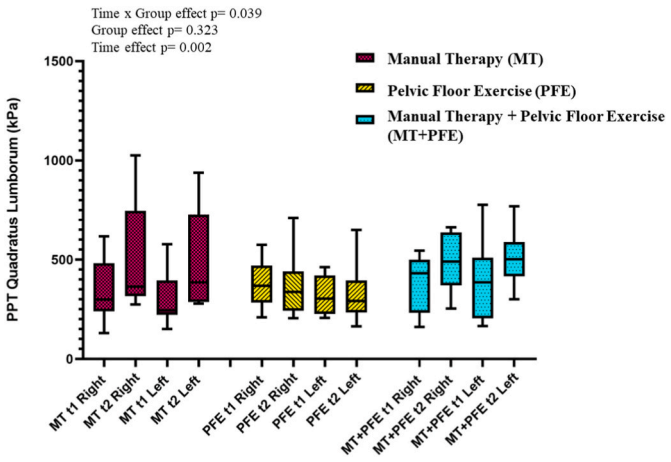

Fig. 3. Boxplots representing the difference in the muscle quadratus lumborum (m.QL) pressure pain threshold (PPT, kPa) in the manual therapy (n = 10; MT, pink), pelvic floor exercises (n = 10; PFE, yellow) and combined protocol (n = 10; MT + PFE, light blue) groups; pre (t1) and post (t2) refer to the values before and after the treatment; R: right, L: left. Significant time x group effect was found ($F_{2,27} = 3.665$; $p = 0.039$; $p\eta^2 = 0.214$). (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Table 2
SF-36 domains scores of the included participants (n = 30).

	MT (n = 10)	PFE (n = 10)	MT + PFE (n = 10)
SF-36, score			
PF			
pre	75.5 ± 13.4*	69.0 ± 17.9	74.0 ± 17.8*
post	92.0 ± 9.2*	87.0 ± 16.4	92 ± 16.7*
RP			
pre	27.5 ± 27.5*	5.0 ± 10.5*	25.0 ± 31.2*
Post	72.5 ± 38.1*	65.0 ± 42.8*	82.5 ± 26.5*
RE			
pre	36.7 ± 24.6	10.0 ± 16.1*	26.7 ± 41.0*
post	70.0 ± 39.9	50.0 ± 39.3*	56.7 ± 31.6*
BP			
pre	41.0 ± 20.0*	36.8 ± 19.3*	39.0 ± 10.6*
Post	66.3 ± 26.2*	67.8 ± 24.6*	76.3 ± 21.6*
VT			
pre	38.0 ± 17.2*	34.0 ± 13.9*	36.0 ± 14.9*
post	65.0 ± 18.9*	49.0 ± 22.7*	55.0 ± 9.7*
SF			
pre	47.5 ± 21.9*	50.0 ± 11.8*	52.5 ± 17.5*
post	76.3 ± 19.9*	68.8 ± 17.9*	76.3 ± 15.0*
MH			
pre	50.8 ± 16.0*	52.4 ± 12.9	52.4 ± 11.4*
post	76.7 ± 12.6*	62.4 ± 17.9	68.4 ± 12.7*
GH			
pre	75.5 ± 15.7	79.5 ± 14.0	78.0 ± 14.9
post	79.5 ± 17.6	79.0 ± 14.3	77.0 ± 17.8

Notes: Italian version of the SF-36 to investigate different aspects of the quality of life from 0 to 100 (physical functioning, PF; role-physical, RP; role-emotional, RE; bodily pain, BP; general health, GH; vitality, VT; social functioning, SF; mental health, MH) (Apolone and Mosconi, 1998). MT: manual therapy, PFE: pelvic floor exercises, MT + PFE: combined. *p < 0.05 for within-group significance (time).

4. Discussion

4.1. Oveall interpreation of results

Primary dysmenorrhea is often characterized by pain, that can be present both in pelvic and lumbar body areas, as well as overall reduced quality of life. The results from this study suggest that non-

pharmacological treatments, such as physiotherapy protocols, could be effective in mitigating some of these symptoms. In particular, we compared the efficacy of three different protocols, one including manual therapy procedures, one including pelvic floor exercise, and one combining the two protocols. The main findings of this study show that all three proposed protocols decreased pain sensation and quality of life in women with primary dysmenorrhea. However, pelvic floor exercise seems to be less effective to improve the pressure pain threshold in lumbar muscles compared to manual therapy or the combined protocol, although this was not reflected in the NRS of lumbar pain, which showed similar improvement in all three protocols.

4.2. Pain

In some studies, the correlation between clinical measures of pain, such as subjective reports of pain intensity, and quantitative measures of pain sensation, such as quantitative sensory testing and PPT, has been questioned for weak associations (Hübscher et al., 2013). In particular, it has been argued that the application of physical pressure in the PPT could result in measures that do not correlate with subjective ratings based on a chronic evaluation of pain (Rebbeck et al., 2015). As such, it might be speculated that this difference between the effect of active exercise on lumbar pain between NRS subjective reporting and PPT might depend on the above-mentioned factors. Pelvic floor exercises might improve the overall quality of life and health status, modulating subjective perception of pain. Indeed, whereas PPT investigates the response to a mechanical pressure stimulus on a selected muscle, NRS reports pain during daily life and might better respond to pelvic floor exercise. In addition, the manual therapy techniques were primarily delivered on low back areas, and this might have provided not only an overall benefit on subjective pain sensation but might have also influenced PPT scores.

Spinal manipulation and manual pressure release could improve pain sensitivity in people with musculoskeletal pain since they might act on the excitatory threshold of the mechanoreceptors (Barassi et al., 2021; Haavik and Murphy, 2012). As such, changes in pain sensitivity following spinal manipulative therapy might depend on the reconditioning of muscular tissues, a decrease of mechanical pain sensitivity independent of clinical outcome (neurophysiological), and a decrease as a reflection of the clinical outcome (Goubert et al., 2018; Nim et al., 2021). The results from the present study suggest manual therapy to reduce pain and improve quality of life in women with primary dysmenorrhea; such findings are in-line with previous literature providing similar recommendations (Azima et al., 2015; Özgül et al., 2018).

Active exercise has been often recommended due to systemic benefits which might result in overall improved quality of life and health; in addition, active exercises can also be performed autonomously by the patients and might stimulate a more active and healthier lifestyle. Isometric exercises, stretching exercises, and dynamic treatments have been shown to improve the symptoms and quality of life of sedentary women with primary dysmenorrhea, thereby aiding the prevention of numerous other complications that may arise due to the lack of physical exercise (Carroquino-Garcia et al., 2019; Ortiz et al., 2015; Tharani et al., 2018). In the present study, we observed as the pelvic floor exercise protocol was effective in improving subjective pain sensation and quality of life, although it had limited effect on PPT. Some previous results have suggested small to moderate effects of exercise on pain threshold in healthy subjects (Pacheco-Barrios et al., 2020), and in some people with chronic conditions (Leźnicka et al., 2022; Tan et al., 2022). The mechanistic effects of pain modulation following active exercise might include an improvement of overall health status, and the enhancing of central descending inhibitory functioning (Zheng et al., 2021). In particular, exercises that are focused on the pelvic floor muscles could result in significant improvements inin pain and menstrual attitudes, possibly acting by strengthening the pelvic floor muscles (Boztaş Elverişli et al., 2022; Nasri et al., 2016; Ortiz et al., 2015). In the present study we observed minimal effects of the pelvic floor exercise protocol on the PPT of the selected muscles, suggesting that it was not sufficient to affect pain perception when a mechanical pressure stimulus was applied, although it was effective to improve subjective pain perception. It might be speculated that the volume of treatment (8 h) was not sufficient to induce the neurophysiological alterations that might be observed after exercise protocols on pain modulation.

4.3. Quality of life

According to the literature, quality of life is reduced in females with primary dysmenorrhea (Karanth and Liya, 2018), and in particular, except for social functioning, role–emotional, and mental health domains, the SF-36 points received from the other domains were higher in females with dysmenorrhea (Unsal et al., 2010). Low-dose estrogen/progestin resulted in significanrt improvements in mental component summary and 7/8 domains (role physical, bodily pain, general health, role emotional, mental health, vitality, and social functioning) (Yoshino et al., 2022). Similarly, yoga was found to improve quality of life, as determined by better SF-36 scores compared to a control group, and particular in the functional capacity, vitality, mental health, social aspects, pain and general health components (Yonglitthipagon et al., 2017). In the present study, taken together all the proposed protocols were found to significantly improve the SF-36 quality of life domains, with exceptions made for the general health component. Although no significant group differences were found in the mixed-factors analysis, there is a trend suggesting that manual therapy might be less effective in the role-emotional domain, whereas the pelvic floor exercise protocol performed worse in the physical function and mental health domains. In contrast, the combined protocol was found to be able to improve all the SF-36 components (except the general health as above-mentioned).

4.4. Limitations

This study presents some limitations, mainly related to the small sample size. Indeed, only ten participants were included for each treatment protocol, and interindividual differences should be considered especially in subjective reporting of symptoms. Although all the participants were carefully instructed to refrain from taking any drug or other medications during the study period, it should be considered that it might have been possible any other therapy might have influenced the results. In addition, the observational nature of the study cannot exclude that, since the participants voluntarily decided in which treatment protocol participate, this might have influenced their results. However, no significant differences between the three groups were found at baseline for most of the outcomes, despite some SF-36 subdomains presented some differences (in particular the role physical and role emotional domains). Finally, the treatments were performed for a short period of time, and longer protocols of treatment might result in different findings. In addition, a follow-up might have helped to describe the duration of the effects of the treatments.

Since the efficacy of the two proposed protocols to improve different aspects of pain and quality of life in women with primary dysmenorrhea, with some differences in the magnitude of the effects, the combination of manual therapy and pelvic floor exercise presented a good rationale for its efficacy. Indeed, when the combined protocols were proposed, it resulted in a significant improvement of all the outcomes, with a magnitude similar to that observed after the single protocol of treatment which produced a greater effect. This was of particular interest, as it was obtained despite the volume of treatment being similar to that of the single protocol, meaning that only half of the time during the combined treatment was dedicated to implementing the manual therapy and techniques, and half of the time was dedicated to pelvic floor exercise. To the best of the authors' knowledge and according to a recent

systematic review, this is the first study attempting to show the effects of a combined manual therapy and pelvic floor exercise in people with primary dysmenorrhea (López-Liria et al., 2021). As such, it might be suggested that combining the two protocols of treatment, without the need to increase the duration or frequency of treatments, was effective in improving pain and quality of life outcomes by including all the benefits and different aspects of the two different protocols, and therefore should be recommended to obtain the most advantageous results in the different health aspects of women with primary dysmenorrhea.

5. Conclusions

Among the non-pharmacological treatments for primary dysmenorrhea, physiotherapy offers several opportunities thanks to the wide choice of therapies, mainly non-invasive and well-accepted by the subjects. This study shows that manual therapy and pelvic floor exercise can improve clinical and pain outcomes, the latter being considered both as subjective perception and objective measures of pain. The combined protocol, performed at similar total volume of treatment, offer the best opportunity since it provides all the benefits of the two individual techniques.

Compliance with ethical standards

The research was conducted according to the principles of the Declaration of Helsinki. All the participants released their informed consent after all procedures had been fully explained. This study was approved by the [omitted for review only] Ethical Board.

Data availability statement

Anonymized data are available upon reasonable request to the corresponding author according to the standard institutional procedure.

CRediT authorship contribution statement

Manuela Deodato: Conceptualization, Data curation, Methodology, Software, Supervision, Visualization, Writing – original draft, Writing – review & editing. **Giulia Grosso:** Conceptualization, Investigation, Writing – original draft. **Alice Drago:** Conceptualization, Investigation, Writing – original draft. **Miriam Martini:** Data curation, Formal analysis, Methodology, Visualization, Writing – original draft, Writing – review & editing. **Erica Dudine:** Conceptualization, Supervision, Investigation, Writing – review & editing. **Luigi Murena:** Methodology, Resources, Supervision, Validation, Writing – review & editing. **Alex Buoite Stella:** Data curation, Formal analysis, Methodology, Resources, Software, Supervision, Validation, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The author declares no conflicts of interest.

References

Abaraogu, U.O., Igwe, S.E., Tabansi-Ochiogu, C.S., Duru, D.O., 2017. A systematic review and meta-analysis of the efficacy of manipulative therapy in women with primary dysmenorrhea. Explore. https://doi.org/10.1016/j.explore.2017.08.001.

Alfonsin, M.M., Chapon, R., de Souza, C.A.B., Genro, V.K., Mattia, M.M.C., Cunha-Filho, J.S., 2019. Correlations among algometry, the visual analogue scale, and the numeric rating scale to assess chronic pelvic pain in women. Eur. J. Obstet. Gynecol. Reprod. Biol. X 3. https://doi.org/10.1016/j.eurox.2019.100037.

Apolone, G., Mosconi, P., 1998. The Italian SF-36 Health Survey: translation, validation and norming. J. Clin. Epidemiol. 51, 1025–1036. https://doi.org/10.1016/s0895-4356(98)00094-8.

Armour, M., Ee, C.C., Naidoo, D., Ayati, Z., Chalmers, K.J., Steel, K.A., de Manincor, M.J., Delshad, E., 2019. Exercise for dysmenorrhoea. Cochrane Database Syst. Rev. https://doi.org/10.1002/14651858.CD004142.pub4.

Azima, S., Bakhshayesh, H.R., Kaviani, M., Abbasnia, K., Sayadi, M., 2015. Comparison of the effect of massage therapy and isometric exercises on primary dysmenorrhea: a randomized controlled clinical trial. J. Pediatr. Adolesc. Gynecol. 28 https://doi.org/10.1016/j.jpag.2015.02.003.

Aziz, K.S.A., Mowafy, H.E.S.M., Hasanin, M.E., Ghazal, N.H.H.M., 2021. Effect of muscle energy technique versus aerobic exercise on chronic cyclic pelvic pain. Egypt. J. Hospit. Med. 84 https://doi.org/10.21608/EJHM.2021.181212.

Barassi, G., Pokorski, M., Matteo, C. di, Supplizi, M., Prosperi, L., Guglielmi, V., Younes, A., della Rovere, F., Iorio, A. di, 2021. Manual pressure release and low-grade electrical peripheral receptor stimulation in nonspecific low back pain: a randomized controlled trial. In: Advances in Experimental Medicine and Biology. https://doi.org/10.1007/5584_2020_605.

Barcikowska, Z., Grzybowska, M.E., Wąż, P., Jaskulak, M., Kurpas, M., Sotomski, M., Starzec-Proserpio, M., Rajkowska-Labon, E., Hansdorfer-Korzon, R., Zorena, K., 2022. Effect of manual therapy compared to ibuprofen on primary dysmenorrhea in young women—concentration assessment of C-reactive protein, vascular endothelial growth factor, prostaglandins and sex hormones. J. Clin. Med. 11, 2686. https://doi.org/10.3390/jcm11102686.

Bourdel, N., Alves, J., Pickering, G., Ramilo, I., Roman, H., Canis, M., 2015. Systematic review of endometriosis pain assessment: how to choose a scale? Hum. Reprod. Update 21. https://doi.org/10.1093/humupd/dmu046.

Boztaş Elverişli, G., Armağan, N., Atilgan, E., 2022. Comparison of the efficacy of pharmacological and nonpharmacological treatments in women with primary dysmenorrhea: randomized controlled parallel-group study. Ginekol. Pol. https://doi.org/10.5603/gp.a2022.0009.

Carroquino-Garcia, P., Jiménez-Rejano, J.J., Medrano-Sanchez, E., de La Casa-Almeida, M., Diaz-Mohedo, E., Suarez-Serrano, C., 2019. Therapeutic exercise in the treatment of primary dysmenorrhea: a systematic review and meta-analysis. Phys. Ther. https://doi.org/10.1093/ptj/pzz101.

Castien, R.F., Coppieters, M.W., Durge, T.S.C., Scholten-Peeters, G.G.M., 2021. High concurrent validity between digital and analogue algometers to measure pressure pain thresholds in healthy participants and people with migraine: a cross-sectional study. J. Headache Pain 22. https://doi.org/10.1186/s10194-021-01278-8.

Chen, C.X., Kwekkeboom, K.L., Ward, S.E., 2015. Self-report pain and symptom measures for primary dysmenorrhoea: a critical review. Eur. J. Pain. https://doi.org/10.1002/ejp.556 (United Kingdom).

Deodato, M., Granato, A., Borgino, C., Galmonte, A., Manganotti, P., 2022a. Instrumental assessment of physiotherapy and onabolulinumtoxin-A on cervical and headache parameters in chronic migraine. Neurol. Sci. 43 https://doi.org/10.1007/s10072-021-05491-w.

Deodato, M., Granato, A., Ceschin, M., Galmonte, A., Manganotti, P., 2022b. Algometer assessment of pressure pain threshold after onabotulinumtoxin-A and physical therapy treatments in patients with chronic migraine: an observational study. Front. Pain Res. 3, 770397.

Deŕman, O., Kanbur, N.Ö., Baltaci, G., Akbayrak, T., Tokur, T., 2004. The pain intensity level in adolescents with primary dysmenorrhea. Pain Clin. 16 https://doi.org/10.1163/1568569041798353.

Fernández-Martínez, E., Onieva-Zafra, M.D., Parra-Fernández, M.L., 2019. The impact of dysmenorrhea on quality of life among Spanish female university students. Int. J. Environ. Res. Publ. Health 16. https://doi.org/10.3390/ijerph16050713.

Ferries-Rowe, E., Corey, E., Archer, J.S., 2020. Primary dysmenorrhea: diagnosis and therapy. Obstetrics and gynecology. https://doi.org/10.1097/AOG.0000000000004096.

García-Peñalver, U.J., Palop-Montoro, M.V., Manzano-Sánchez, D., 2020. Effectiveness of the muscle energy technique versus osteopathic manipulation in the treatment of sacroiliac joint dysfunction in athletes. Int. J. Environ. Res. Publ. Health 17. https://doi.org/10.3390/ijerph17124490.

Goubert, D., Meeus, M., Willems, T., de Pauw, R., Coppieters, I., Crombez, G., Danneels, L., 2018. The association between back muscle characteristics and pressure pain sensitivity in low back pain patients. Scand J. Pain. 18 https://doi.org/10.1515/sjpain-2017-0142.

Haavik, H., Murphy, B., 2012. The role of spinal manipulation in addressing disordered sensorimotor integration and altered motor control. J. Electromyogr. Kinesiol. https://doi.org/10.1016/j.jelekin.2012.02.012.

Harel, Z., 2006. Dysmenorrhea in adolescents and young adults: etiology and management. J. Pediatr. Adolesc. Gynecol. https://doi.org/10.1016/j.jpag.2006.09.001.

Hübscher, M., Moloney, N., Leaver, A., Rebbeck, T., McAuley, J.H., Refshauge, K.M., 2013. Relationship between quantitative sensory testing and pain or disability in people with spinal pain - a systematic review and meta-analysis. Pain. https://doi.org/10.1016/j.pain.2013.05.031.

Iacovides, S., Avidon, I., Baker, F.C., 2015. What we know about primary dysmenorrhea today: a critical review. Hum. Reprod. Update 21. https://doi.org/10.1093/humupd/dmv039.

Jafari, H., Courtois, I., van den Bergh, O., Vlaeyen, J.W.S., van Diest, I., 2017. Pain and respiration: a systematic review. Pain. https://doi.org/10.1097/j.pain.0000000000000865.

Kannan, P., Claydon, L.S., 2014. Some physiotherapy treatments may relieve menstrual pain in women with primary dysmenorrhea: a systematic review. J. Physiother. 60 https://doi.org/10.1016/j.jphys.2013.12.003.

Karanth, S., Liya, S.R., 2018. Prevalence and risk factors for dysmenorrhoea among nursing student and its impact on their quality of life. Int J Reprod Contracept Obstet Gynecol 7. https://doi.org/10.18203/2320-1770.ijrcog20182483.

Karcioglu, O., Topacoglu, H., Dikme, Ozgur, Dikme, Ozlem, 2018. A systematic review of the pain scales in adults: which to use? AJEM (Am. J. Emerg. Med.). https://doi.org/10.1016/j.ajem.2018.01.008.

Leźnicka, K., Pawlak, M., Maciejewska-Skrendo, A., Buczny, J., Wojtkowska, A., Pawlus, G., Machoy-Mokrzyńska, A., Jażdżewska, A., 2022. Is physical activity an effective factor for modulating pressure pain threshold and pain tolerance after cardiovascular incidents? Int. J. Environ. Res. Publ. Health 19, 11276. https://doi.org/10.3390/ijerph191811276.

López-Liria, R., Torres-álamo, L., Vega-Ramírez, F.A., García-Luengo, A.v., Aguilar-Parra, J.M., Trigueros-Ramos, R., Rocamora-Pérez, P., 2021. Efficacy of physiotherapy treatment in primary dysmenorrhea: a systematic review and meta-analysis. Int. J. Environ. Res. Publ. Health. https://doi.org/10.3390/ijerph18157832.

Machado, A.F.P., Perracini, M.R., Rampazo, É.P., Driusso, P., Liebano, R.E., 2019. Effects of thermotherapy and transcutaneous electrical nerve stimulation on patients with primary dysmenorrhea: a randomized, placebo-controlled, double-blind clinical trial. Compl. Ther. Med. 47 https://doi.org/10.1016/j.ctim.2019.08.022.

McNamara, C.A., 2000. Travell & simons' myofascial pain and dysfunction: the trigger point manual, volume 1: upper half of body, ed 2. Phys. Ther. 80.

Nasri, M., Barati, A.H., Ramezani, A., 2016. The effects of aerobic training and pelvic floor muscle exercise on primary dysmenorrhea in adolescent girls. J. Clin. Nurs. Midwifery 5.

Newham, D., 1992. Myofascial Pain and Dysfunction: vol 2: the trigger point manual — the lower extremities. Physiotherapy 78. https://doi.org/10.1016/s0031-9406(10)61231-x.

Nim, C.G., Kawchuk, G.N., Schiøttz-Christensen, B., O'Neill, S., 2021. Changes in pain sensitivity and spinal stiffness in relation to responder status following spinal manipulative therapy in chronic low Back pain: a secondary explorative analysis of a randomized trial. BMC Muscoskel. Disord. 22 https://doi.org/10.1186/s12891-020-03873-3.

Ortiz, M.I., Cortés-Márquez, S.K., Romero-Quezada, L.C., Murguía-Cánovas, G., Jaramillo-Díaz, A.P., 2015. Effect of a physiotherapy program in women with primary dysmenorrhea. Eur. J. Obstet. Gynecol. Reprod. Biol. 194 https://doi.org/10.1016/j.ejogrb.2015.08.008.

Özgül, S., Üzelpasaci, E., Orhan, C., Baran, E., Beksaç, M.S., Akbayrak, T., 2018. Short-term effects of connective tissue manipulation in women with primary dysmenorrhea: a randomized controlled trial. Compl. Ther. Clin. Pract. 33 https://doi.org/10.1016/j.ctcp.2018.07.007.

Pacheco-Barrios, K., Gianlorenço, A.C., Machado, R., Queiroga, M., Zeng, H., Shaikh, E., Yang, Y., Nogueira, B., Castelo-Branco, L., Fregni, F., 2020. Exercise-induced pain threshold modulation in healthy subjects: a systematic review and meta-analysis. Princip. Pract. Clin. Res. J. 6 https://doi.org/10.21801/ppcrj.2020.63.2.

Park, G., Kim, C.W., Park, S.B., Kim, M.J., Jang, S.H., 2011. Reliability and usefulness of the pressure pain threshold measurement in patients with myofascial pain. Ann. Rehabil. Med. 35 https://doi.org/10.5535/arm.2011.35.3.412.

Petraglia, F., Bernardi, M., Lazzeri, L., Perelli, F., Reis, F.M., 2017. Dysmenorrhea and related disorders. https://doi.org/10.12688/f1000research.11682.1. F1000Res.

Rebbeck, T., Moloney, N., Azoory, R., Hübscher, M., Waller, R., Gibbons, R., Beales, D., 2015. Clinical ratings of pain sensitivity correlate with quantitative measures in people with chronic neck pain and healthy controls: cross-sectional study. Phys. Ther. 95 https://doi.org/10.2522/ptj.20140352.

Rocha, T., Souza, H., Brandão, D.C., Rattes, C., Ribeiro, L., Campos, S.L., Aliverti, A., de Andrade, A.D., 2015. The Manual Diaphragm Release Technique improves diaphragmatic mobility, inspiratory capacity and exercise capacity in people with chronic obstructive pulmonary disease: a randomised trial. J. Physiother. 61 https://doi.org/10.1016/j.jphys.2015.08.009.

Slater, H., Paananen, M., Smith, A.J., O'Sullivan, P., Briggs, A.M., Hickey, M., Mountain, J., Karppinen, J., Beales, D., 2015. Heightened cold pain and pressure pain sensitivity in young female adults with moderate-to-severe menstrual pain. Pain 156. https://doi.org/10.1097/j.pain.0000000000000317.

Stull, D.E., Wasiak, R., Kreif, N., Raluy, M., Colligs, A., Seitz, C., Gerlinger, C., 2014. Validation of the SF-36 in patients with endometriosis. Qual. Life Res. 23 https://doi.org/10.1007/s11136-013-0442-5.

Tan, L., Cicuttini, F.M., Fairley, J., Romero, L., Estee, M., Hussain, S.M., Urquhart, D.M., 2022. Does aerobic exercise effect pain sensitisation in individuals with musculoskeletal pain? A systematic review. BMC Muscoskel. Disord. 23 https://doi.org/10.1186/s12891-022-05047-9.

Tharani, G., Dharshini, E., Rajalaxmi, V., Kamatchi, K., Vaishnavi, G., 2018. To compare the effects of stretching exercise versus aerobic dance in primary dysmenorrhea among collegiates. Drug Invent. Today 10.

Unsal, A., Ayranci, U., Tozun, M., Arslan, G., Calik, E., 2010. Prevalence of dysmenorrhea and its effect on quality of life among a group of female university students. Ups. J. Med. Sci. 115 https://doi.org/10.3109/03009730903457218.

Yonglitthipagon, P., Muansiangsai, S., Wongkhumngern, W., Donpunha, W., Chanavirut, R., Siritaratiwat, W., Mato, L., Eungpinichpong, W., Janyacharoen, T., 2017. Effect of yoga on the menstrual pain, physical fitness, and quality of life of young women with primary dysmenorrhea. J. Bodyw. Mov. Ther. 21 https://doi.org/10.1016/j.jbmt.2017.01.014.

Yoshino, O., Takahashi, N., Suzukamo, Y., 2022. Menstrual symptoms, health-related quality of life, and work productivity in Japanese women with dysmenorrhea receiving different treatments: prospective observational study. Adv. Ther. 39 https://doi.org/10.1007/s12325-022-02118-0.

Zahradnik, H.P., Breckwoldt, M., 1984. Contribution to the pathogenesis of dysmenorrhea. Arch. Gynecol. 236 https://doi.org/10.1007/BF02134006.

Zahradnik, H.P., Hanjalic-Beck, A., Groth, K., 2010. Nonsteroidal anti-inflammatory drugs and hormonal contraceptives for pain relief from dysmenorrhea: a review. Contraception. https://doi.org/10.1016/j.contraception.2009.09.014.

Zheng, K., Chen, C., Yang, S., Wang, X., 2021. Aerobic exercise attenuates pain sensitivity: an event-related potential study. Front. Neurosci. 15 https://doi.org/10.3389/fnins.2021.735470.