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Potential effects of combining osteopathic manual therapy and menstrual awareness on pain and associated symptoms in women with primary dysmenorrhea: A randomized clinical trial

María Conesa-Albaladejo [a,1], Gemma Victoria Espí-López [a,b,*,1], Eva Martínez-Graullera [a], Anna Arnal-Gómez [a,c]

[a] Department of Physiotherapy, Faculty of Physiotherapy, University of Valencia, Gascó Oliag St, 5, 46010, Valencia, Spain
[b] Exercise Intervention for Health Research Group (EXINH-RG), Department of Physiotherapy, University of Valencia, 46010, Valencia, Spain
[c] Physiotherapy in Motion. Multispeciality Research Group (PTinMOTION), Department of Physiotherapy, University of Valencia, Gascó Oliag St, 5, 46010 Valencia, Spain

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ABSTRACT

Background: Dysmenorrhea is a menstrual condition that accounts for 50–90 % of all gynaecological consultations and is the most common gynaecological condition among young women. Lack of information regarding treatment options can affect the symptoms and quality of life of women who suffer from it. Osteopathic manual therapy could be a treatment option to improve symptoms in primary dysmenorrhea.
Objective: The aim of this study was to apply an osteopathic manual therapy protocol to reduce menstrual pain and other symptoms related to primary dysmenorrhea.
Methods: A randomized clinical trial was conducted. Thirty-nine female volunteers diagnosed with primary dysmenorrhea, with a mean age of 30.4 years (SD = 5.67), were randomly assigned to two groups: an experimental group (n = 19) who received body awareness plus osteopathic manual therapy and a comparator group (n = 20) who received only body awareness. Pain intensity (Visual Analogue Scale), pain perception (the McGill Pain Questionnaire), quality of life (36-Item Short Form Survey Instrument), body satisfaction (Body Satisfaction and Global Self-Perception Questionnaire), and overall perception of change (Patient Global Impression of Change Scale) were assessed pre- and post-treatment.
Results: Comparing both groups, the experimental group showed a statistically significant improvement in pain intensity ($p = 0.007$), pain perception ($p = 0.025$), quality of life ($p < 0.001$), and body satisfaction ($p < 0.001$). In addition, most women in the experimental group (94.7 %) perceived a positive change after treatment, while most of the comparator group (65 %) reported no changes.
Conclusion: An osteopathic manual therapy protocol combined with body awareness revealed significant improvements in terms of pain and other symptoms in women with dysmenorrhea.

Implications for Practice

- Dysmenorrhea causes psychological, physical, behavioural and social discomfort.
- The menstrual awareness sessions carried out improve some aspects of dysmenorrhea.
- When osteopathic manual therapy was added to menstrual awareness sessions, there is higher improvements in intensity and perception of pain, body satisfaction, global self-perception and quality of life.
- The impact of the study focuses on women suffering from dysmenorrhea and offers a valid complementary option for healthcare and pain management in this population.

* Corresponding author. Department of Physiotherapy, Faculty of Physiotherapy. University of Valencia. Gascó Oliag Street, 5, 46010, Valencia, Spain.
E-mail addresses: marsolunas@gmail.com (M. Conesa-Albaladejo), gemma.espi@uv.es (G.V. Espí-López), evamartinez788@gmail.com (E. Martínez-Graullera), anna.arnal@uv.es (A. Arnal-Gómez).
[1] Same contributions.

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1. Introduction

Dysmenorrhea is a menstrual condition that is defined as intense uterine pain that presents as lower abdominal pain. Other symptoms may include dizziness, nausea, vomiting, diarrhoea, headaches, swelling, lumbosacral pain, and pain in the inner leg regions [1]. When the pain occurs during the menstrual cycle, over more than 6 months, and in the absence of other pathologies, it is classified as primary dysmenorrhea [2], and it represents between 50 and 90 % of all gynaecological consultations [3]. It is also characterized by psychological, physical, behavioural and social distress [4,5] and can negatively affect one's quality of life [6]. Secondary dysmenorrhea is menstrual pain caused by an underlying disease, disorder, or structural abnormality within or outside the uterus [7].

Currently the most common treatment is based on non-steroidal anti-inflammatory drugs (NSAIDs) or anovulatory drug intake [8]. However, other adjuvant treatment options that may help to alleviate the symptoms have been explored [9]. In this sense, awareness and behavioural approach-based sessions have shown to alleviate pain intensity and the reduction of drug intake [10]. To reduce symptoms, the application of several manual therapy (MT) methods have been proposed, such as rhythmic massage [11], pelvis manipulation [12], MT based on osteopathic treatment (OMT) [13], craniosacral techniques [14], and connective tissue manipulation with stretching exercises [15]. The osteopathic treatment in the abdominal area, which includes direct techniques, indirect techniques and visceral and/or cranial techniques, provided benefits in terms of the intensity and duration of pain, improvements in quality of life scores, decreased drug intake [13] and overall well-being [14]. However, the benefits of these techniques in other areas that may also impact the lives of women with dysmenorrhea have not been studied, to the best of our knowledge. In addition to evaluating pain intensity, the study of pain perception can also be of importance, as previously studied [16,17], but not with the application of osteopathic manual therapy. Measuring pain perception is crucial. It provides a more complete understanding of the patient's experience because it includes quantitative and qualitative aspects of pain that influence how pain is experienced and responded to Ref. [18]. Body image has been shown to be an issue for women with endometriosis [7] and women in menopause [19]; dysmenorrhea can also lead to a distorted perception of one's body image and general body dissatisfaction. It is also important to take into account the evaluation of quality of life, as well as to ascertain the perception of the change after carrying out a treatment.

Osteopathic craniosacral techniques are a set of non-invasive fascial techniques performed between the skull and the sacrum [20]. Specifically, the CV4 technique can be beneficial for pain and in patients with different functional problems [23–25]. However, it has not been applied to dysmenorrhea, nor has it been evaluated on key areas that have an impact on women who suffer from it. Craniosacral and myofascial techniques have the objective of relaxing myofascial structures and normalize sympathetic nerve activation and are often increased in patients with chronic pain [21,22]. In this line, there is a relationship between menstrual pain and pelvic alignment, justifying its manipulation [26,27]. Since dysmenorrhea causes pelvic pain [28], including myofascial techniques in its treatment could be an optimal option to reduce the menstrual pain process; however, there are no studies that conclude this hypothesis in women with dysmenorrhea.

Moreover, there are important gaps regarding knowledge and self-care in menstrual cycles [30]. So, it is extremely important that women are adequately informed about menstruation and dysmenorrhea. This information could contribute to women having more positive attitude towards their symptoms and reduce the negative effects of social stigma on menstrual health literacy [31]. However, regarding the possible treatments based on MT, previous studies conducted on women with dysmenorrhea do not clearly conclude effectiveness with sufficient methodological quality [32].

Therefore, we hypothesize that an OMT protocol, based on techniques used to reduce pain symptoms, which includes craniosacral, myofascial and visceral techniques combined with body awareness sessions, will reduce the symptoms of primary dysmenorrhea and associated variables. The aim of this study was to evaluate the effect of an OMT protocol and body awareness, compared with only body awareness, on intensity and perception of pain, quality of life, perception of change, and body satisfaction in women with primary dysmenorrhea.

2. Methods

2.1. Study population

The study involved women diagnosed with dysmenorrhea recruited over 8 months from the gynaecology public health services of Valencian Community (Spain). Women were included if they had a diagnosis of primary dysmenorrhea, with more than 6 months of evolution, and with moderate or severe pain (scoring $\geq$4 on the visual analogue scale, VAS) in more than half of their menstrual cycles during one year [33]. Exclusion criteria were women with secondary dysmenorrhea, women who currently or in the previous twelve months had undergone hormonal treatment, those who were pregnant, women receiving physiotherapeutic treatment at the time of the study, and those for whom any of the planned treatments were contraindicated.

2.2. Study design

A randomized clinical trial was conducted between June and August 2018. Participants were divided into two groups: the Body Awareness (BA) group, which served as the comparator and received two behavioural and menstrual awareness sessions, and the BA + OMT experimental group, which received the same body awareness sessions along with three osteopathic manual therapy sessions (Table 1). The program spanned nine weeks to ensure it included parts of three menstrual cycles and two full menstruations. A physiotherapist and osteopath with over 15 years of experience delivered the treatment. Evaluations were performed at baseline prior to the intervention (T1) and one month after the final intervention (T2). The study took place at the Faculty of Valencia (Spain) and was prospectively registered at ClinicalTrials.gov (Identifier: NCT03593057). Ethical approval was granted by the Ethics Committee of the University of Valencia under protocol number H1512324924513. All participants were provided with detailed information about the study and gave both oral and written consent before participation. The trial adhered to the ethical principles outlined in the Declaration of Helsinki (Helsinki, Finland, June 1964) on Biomedical Research, and the CONSORT 2010 guidelines [34].

2.3. Randomization and blinding

An external assistant, not involved in the research, randomized the distribution of the groups. Opaque envelopes containing the different treatments were distributed among the participants. An independent blind assessor who was unaware of participants' allocation performed the assessment and recorded the data. The assessor provided the questionnaires and clarified any doubts that could arise. A statistician conducted the analysis and interpretation of results.

2.4. Intervention

The body awareness intervention consisted of two face-to-face group sessions, each lasting 45 min, led by a clinician. In these sessions, participants were provided with information on anatomy, basic physiology, and the menstrual cycle process. In addition, information was provided on the phases and concepts of dysmenorrhea, menstruation awareness, self-knowledge and self-care. In the sessions, all women became aware

Table 1
Design of the study phases.

Assessment phase: initial week of baseline assessment.
Intervention phase
Week 1
BA group: Session 1 of BA and access to app and pain information digital folder.
BA + OMT group: Session 1 of BA and access to app and pain information digital folder + Session 1 of OMT.
Week 2
BA group: access to app and pain information digital folder.
BA + OMT group: access to app and pain information digital folder.
Week 3
BA group: access to app and pain information digital folder.
BA + OMT group: Session 2 of osteopathic OMT and access to app and pain information digital folder.
Week 4
BA group: access to app and pain information digital folder.
BA + OMT group: access to app and pain information digital folder.
Week 5
BA group: access to app and pain information digital folder.
BA + OMT group: access to app and pain information digital folder.
Week 6
BA group: Session 2 of BA + access to pain education folder.
BA + OMT group: Session 2 of BA + Session 3 of OMT and access to app and pain information digital folder.
Week 7 – Week 9
BA group: access to app and pain information digital folder.
BA + OMT group: access to app and pain information digital folder.
Assessment phase: final week of assessment.

BA: Body awareness; OMT: osteopathic manual therapy.

of their own menstrual cycle and they were provided with tools to be able to better self-manage menstrual pain [35]. In addition, a mobile application was used to register the changes occurring during their menstrual cycle (Clue (https://helloclue.com/es), such as the length of menstruation, pain intensity, and other menstrual cycle symptoms, so the women could be more aware of them during the weeks of the program. Also, they were given access to a shared online information folder (see Supplementary material) which included concepts related to pain and to the menstrual cycle and its phases, information on dysmenorrhea, information on pharmacological and non-pharmacological treatments, bibliographic references, and an email account to contact the researchers if needed.

The OMT intervention consisted of three sessions lasting 45 min each. The OMT-applied protocol included several techniques (Appendix I).

- *The global pelvic manipulation technique*. It is a semi-direct technique of high-speed and low amplitude, aimed at restoring overall mobility in the lumbosacral region [12,36]. It produces an opening of the sacroiliac joint (SIJ) and of the facet joint of the fifth lumbar vertebra on the first sacral vertebra (L5-S1). This maneuver has been used by other authors in dysmenorrhea [12]. These techniques are applied for 2 min.
- *Compression of fourth ventricular (CV-4) technique* [37] which has the aim of improving cranial rhythmic function and lymphatic flow. It may also relax the tone of the sympathetic nervous system to a significant degree [38,39]. This technique of bringing the subject to a still point was repeated as many times as allowed over a total of 10 min [40]. This technique has been used by other authors in women [41], as well as patients with headaches [40] and high blood pressure [42].
- *Myofascial and visceral release techniques* [12,43] was applied in the abdominal region, aiming to release fascial restriction zones in the abdominal area caused by pain and pelvic inflammation [29,44]. For this study, we chose the following, which lasted approximately 30 min:

a) Release of the broad ligament with lower lever. This aims to improve side-to-side mobility of the uterus and local decongestion. This mobilizes the adhesions to the inferior hypogastric plexus. It is performed in both directions [45] over 5 min. This technique has been previously applied in dysmenorrhea [45]; b) *Release of the broad ligament, vesico-uterine fundus, and tube-ovarian ligament.* This technique mobilizes the abdominal contents, covering the genitourinary structures and fallopian tubes [45]. This technique has been applied previously in women with dyspareunia [46]. It was applied for 5 min; c) *Mobilization of the Douglas cul-de-sac.* Access to this space is done intra-vaginally, but there is evidence in the literature of the positive effects of external techniques [45]; This technique releases adhesions in the structures [47] and was applied for 5 min; d) *Abdominal hemodynamic maneuver.* Dysmenorrhea is characterized, among other causes, by poor irrigation of the womb [2]. This maneuver aims to mobilize fluids from the abdomen, taking advantage of the patient's breathing and diaphragmatic mobilization, which is why this technique acts as a lymphatic pump, improving blood and lymphatic circulation [48]. This technique was performed for 2 min. [29]; e) *Transverse plane technique.* The fascial system provides support and integrity to the womb, as well as irrigation and innervation. It is mainly through this system that the nervous, arterial, lymphatic and venous supply of the reproductive system is obtained [44]. This technique is applied to return mobility and functionality to the uterus after having eliminated possible adhesions in the previous techniques and is recommended for the fascial arrangement of the pelvic structures [49]. It was applied for 10 min.

2.5. Outcomes

First, the anthropometric variables were registered (age, weight, height, and body mass index [BMI]). Data were also collected on the clinical characteristics of menstrual cycles, medication, and the satisfaction with oral medication on a scale of 0–10.

The following assessments were carried out for both groups at baseline before the start of the intervention, and one month after the last intervention.

2.5.1. Primary outcome

Pain. A VAS was used. The patient rated her perceived pain intensity of the dysmenorrhea from 0 to 10, with 0 being "no pain" and 10 "the maximum pain imaginable or very intense pain". It was measured on the patient's pain intensity from the last menstruation. The VAS has a high internal consistency (0.92) [50].

2.5.2. Secondary outcomes

Perception of pain. The short version of the McGill Pain Questionnaire was used [18] to asses quantitative and qualitative aspects of pain (distribution, quality, intensity, and temporal characteristics) distributed over 4 categories (sensory, emotional, evaluative, and miscellaneous). Different results were obtained: a) Pain Rating Index (PRI), total and for each of the four areas (sensory PRI, emotional PRI, evaluative PRI and miscellaneous PRI); b) Number of words chosen (NWC) (sum of the number of pain characteristics selected by the patient); c) Present Pain Intensity (PPI); and d) Pain intensity according to VAS. In the present study, total PRI and PPI were evaluated with 1 = mild pain and 5 = unbearable pain. The Spanish validation of this questionnaire shows a good internal consistency (0.9) [51].

Personal body satisfaction and global self-perception. Body satisfaction was measured with the Body Satisfaction and Global Self Perception questionnaire adapted to Spanish (QSCPGS*e*) by Espí-López et al. for subjects with non-specific musculoskeletal disorders. This is answered through semantic differentials and includes four factors: Vitality, Aesthetic Appraisal, Cognitive Discomfort, and Affective Discomfort. Higher scores represent a higher level of body satisfaction [52]. The authors make available an online application that generates a graph: http://ivey.az1.qualtrics.com/jfe/form/SV_6LJS0927GOg0bsx.

Quality of life. This was evaluated with the Short Form-36 questionnaire (SF-36) [53] validated to Spanish [54]. It consists of thirty-six items that measure eight dimensions: physical functioning, role functioning/physical, physical pain, role functioning/emotional, social functioning, general health, vitality, and mental health related to quality of life. The Cronbach's alpha of this questionnaire is 0.80 [55]. The scores obtained are converted to a range from 0 to 100.

Global perception of change. It was measured with the Patient Global Impression of Change Scale (PGICS), which evaluates the change perceived after treatment and includes two scales [56]. The first consists of seven items ranging from 1 = "very much improved" to 7 = "very much worse" [57]. The second includes an analogue scale of perception of change. The patient gives a score from 0 to 10, where 0 is "much better" and 10 is "much worse". This scale has been previously used in people with chronic pain [57], and the global rating of change scales have shown excellent retest reliability (ICC = 0.90) [58].

2.6. Statistical analysis and sample size calculation

Statistical analysis was performed with SPSS v. 24 (IBM SPSS, Inc., Chicago, IL, USA). Means, standard deviations, and/or 95 % confidence intervals (CIs) were calculated for continuous variables and the relative distribution for categorical variables. The assumption of homoscedasticity was requested using Levene's test. On the other hand, ANOVA was performed to establish the differences of the mean values before and after the intervention in the entire sample and for each group separately. Calculation and interpretation of the effect size index of the standardized mean difference was carried out. Cohen's d [59] was computed for the effect size, rated as small (0.20–0.50), medium (0.50–0.80), or large (>0.80). For all analyses, the significance level was set at 5 %.

To perform sample size calculation, we took into consideration that we intended to achieve a medium effect size (d = 0.5) of the differences with two groups (BA and BA + OMT) and two assessments (pre, and post-treatment). Further, we set a type I error (α) of 5 %, and a type II error (β) of 20 %. This power calculation resulted in 17 patients in each group. Computer software was used for sample size estimation (G-Power®, Institute for Experimental Psychology, University of Düsseldorf, Düsseldorf, Germany).

3. Results

From the 64 women initially recruited for the study, 40 met the inclusion criteria and were ultimately selected. Before starting the intervention, one participant dropped out due to pregnancy, so finally the sample had a total of 39 participants: BA group (n = 20) and BA + OMT group (n = 19). Once the study started, no participants dropped out and no harmful side effects were observed (Fig. 1).

The mean age of the participants was 30.4 (SD = 5.67), the average weight 62.24 kg (SD = 7.41), the average height 166 cm (SD = 0.07) and the average BMI 22.75 (2.57). Regarding clinical characteristics, there were no statistical differences between groups. All patients reported stomach pain, 69.2 % reported low-back pain, 30.8 % breast pain, 17.9 % headaches, 7.7 % leg pain, and 15.4 % pelvic pain (vulva/vagina pelvic floor). In terms of the evolution of dysmenorrhea, 71.8 % claimed to have suffered from it throughout their lives, 5.1 % in the last 10 years, 15.4 % in the last 5 years and 7.7 % only in the last year. The clinical characteristics are shown in Table 2.

Pain intensity, pain perception, body satisfaction, and quality of life showed no differences between groups in the initial assessment ($p > 0.05$ for all variables). The results after the intervention for pain intensity, pain perception, body satisfaction and quality of life show improvements in both groups. The analysis showed a statistically significant interaction between the factors "treatment group" (BA + OMT and BA) and "time" (pre-treatment and post-treatment) in VAS ($F = 7.780$; $p = 0.008$; $\eta^2 = 0.174$), McGill PRI ($F = 6.260$; $p = 0.017$; $\eta^2 = 0.145$), McGill PPI ($F = 5.772$; $p = 0.021$; $\eta^2 = 0.135$), QoL SF-36 ($F = 13.489$; $p = 0.001$; $\eta^2 = 0.267$), QSCPGS*e* ($F = 11.813$; $p = 0.001$; $\eta^2 = 0.242$). In all cases, effect sizes were large ($d > 0.7$). Post-hoc analysis for all the variables is shown in Table 3.

Regarding perception of change, 42.1 % of the participants of the BA + OMT group claimed to have "very much improved", 52.6 % to have "moderately improved", 65 % "no change", 25 % "slightly improved" and 10 % "moderately improved". Therefore, our results showed greater effectiveness of the combination of OMT with BA.

4. Discussion

The study results showed that the combination of both interventions (BA + OMT) offers significant differences and a medium-high effect size when compared to BA alone in all the variables evaluated (pain intensity, pain perception, body satisfaction, and quality of life). Likewise, the participants perceived a positive change after the combined treatment with an important improvement when compared to the BA group. Accordingly, although the body awareness sessions had positive results, when combined with enhanced OMT results, they are statistically significant.

Regarding pain caused by dysmenorrhea, both the intensity and the perception of pain were evaluated. In this regard, previous studies have demonstrated the effectiveness of awareness and behavioural sessions on pain intensity [31], but the present study is the first to apply the combination of body awareness and OMT obtaining significant results ($p = 0.008$ for VAS; $p = 0.017$ for McGill PRI; $p = 0.021$ for McGill PPI). Additionally, the perception of pain improves globally (Mc Gill PRI) and regarding its intensity (VAS and McGill PPI) in both groups; however, the improvement was significantly higher in the combined group compared to BA alone. To our knowledge, there are no previous studies that assess the perception of pain with the short version of the McGill Pain Questionnaire by applying a OMT protocol in dysmenorrhea that includes craniosacral and myofascial techniques, so this study is unprecedented in terms of specifically evaluating the effects of OMT in connection with pain symptoms related to dysmenorrhea. Other authors reported how a single treatment session applying the bilateral lumbosacral technique (as used in our study) rapidly improved the self-perceived low-back and pelvic pain in women with primary dysmenorrhea [12]. However, only a single technique was applied in a single session to improve low-back pain in women with dysmenorrhea; it did not evaluate other symptoms, and the effectiveness over time was unknown. The present study has implemented a more comprehensive protocol in several sessions and collects long-term evaluations.

On the other hand, the effectiveness of manual therapy in reducing

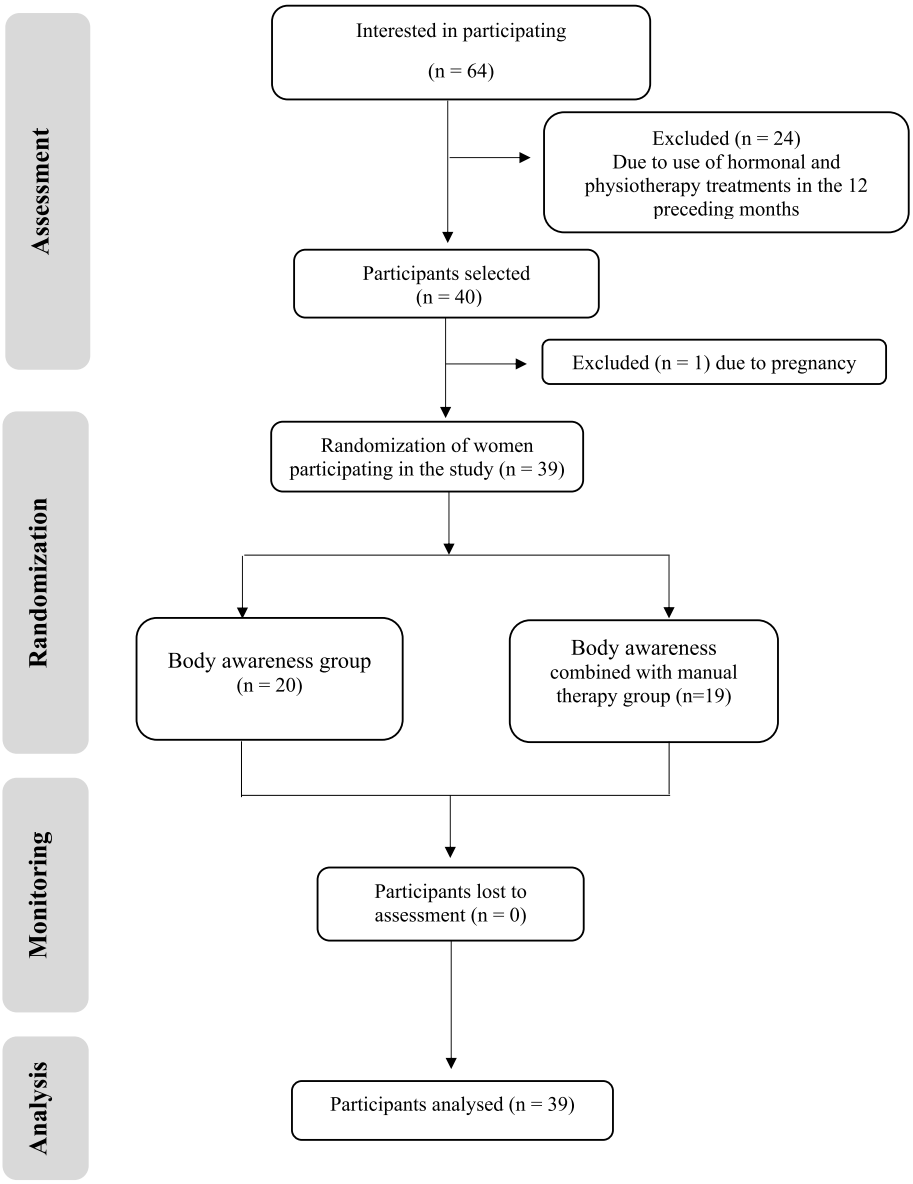

Fig. 1. CONSORT 2010 flow diagram.

Table 2
Clinical characteristics.

	BA (n = 20)	BA + OMT (n = 19)	Total (n = 39)
	m (SD)	m (SD)	m (SD)
Age of start of menarche	12.25 (1.37)	11.68 (1.73)	11.97 (1.56)
Cycle duration	29.20 (3.51)	27.68 (2.14)	28.46 (2.99)
Painful menstruations/ year	8.95 (2.64)	9.95 (2.19)	9.44 (2.90)
Amount of medication	3.6 (3.12)	3 (2.58)	3.31 (SD = 2.85)
Satisfaction with oral medication	6.06 (2.41)	6.69 (2.39)	6.36 (SD = 2.38)

BA. Body awareness group; BA + OMT. Body awareness plus manual therapy group; m: mean; SD: Standard Deviation.

pelvic pain in women with dysmenorrhea has been demonstrated [60]. Thus, in a previous review, the effectiveness of OMT in reducing pain in dysmenorrhea was reported [61], although such results are limited due to methodological flaws. In this regard, our study uses a protocol that combines OMT and body awareness with a longer duration and with a more comprehensive assessment, which leads to more conclusive results.

Regarding body satisfaction, there was an improvement in self-perception ($p = 0.001$ for the QSCPGS*e*). This positive difference is larger in the group that received OMT. This aspect is related to the image perceived by a person of his or her body and the feelings towards it. Thanks to the inclusion of informative sessions on menstruation and dysmenorrhea in both groups, women could have felt more positive about their body satisfaction, although when combined with OMT the results were better. The lack of awareness of one's body in terms of physical, mental, and relational factors may lead to dysfunctional movement, pain, and reduced function [62]. A previous review shows how behavioural interventions can be effective and proposes the need for more clinical trials focused on this topic [10]. The relationship of primary dysmenorrhea with body image distortion has also been demonstrated in women with primary [63] dysmenorrhea. In line with other authors [64], we consider the hypothesis that dysmenorrhea and pain are capable of transmitting a negative body image or body dissatisfaction due to the feeling of lack of health.

Table 3
Pre-post intervention pain values.

	Time	Group BA (n = 20) m (SD)	Group BA + OMT (n = 19) m (SD)	Mean difference between groups (T2) (95 % CI); *p-value*; *d*
VAS	**T1** **T2**	7.97 (1.08) 5.6 (2.34)	7.76 (0.77) 3.52 (2.16)	2.08 (0.61–3.54) ***p* = 0.007** ***d* = 0.842**
McGill PRI	**T1** **T2**	47.1 (19.3) 39.3 (15.81)	48.84 (15.34) 26.57 (18.05)	12.72 (1.72–23.72) ***p* = 0.025** ***d* = 0.710**
McGill PPI	**T1** **T2**	3.55 (1.05) 3 (1.12)	3.89 (1.55) 1.68 (0.67)	1.32 (0.71–1.92) ***p* < 0.001** ***d* = 1.159**
QSCPGS*e* (Total score)	**T1** **T2**	43.45 (13.29) 60.7 (16.27)	44.84 (12.45) 80.42 (10.2)	19.72 (10.85–28.60) ***p* < 0.001 *d* = 1.175** d
QoL SF-36 (Total score)	**T1** **T2**	54.19 (11.93) 59.97 (12.22)	55.38 (10.28) 74.11 (9.99)	14.14 (16.87–21.41) ***p* < 0.001 *d* = 1.073**

BA. Body awareness group; BA + OMT. Body awareness plus osteopathic manual therapy group; m: mean; SD: Standard Deviation; T1. Pre-treatment; T2. Post treatment; VAS. Visual Analogue Scale; McGill PRI. Total Pain Rating Index; McGill PPI. Pain intensity index; QoL. Quality of Life; QSCPGSe. Body satisfaction; p = significant differences between groups at post-intervention; d. effect size with Cohen's d.

In terms of quality of life, the impact of dysmenorrhea in women has been confirmed by other authors [6]. After the proposed treatment, the overall score of both groups improved, with the OMT group obtaining the highest scores. This confirms that OMT improves the musculoskeletal system, which has an impact on quality of life, as revealed in another study [60].

Other authors applied MT in women with dysmenorrhea based on a protocol that included a wide variety of techniques (myofascial release, craniosacral manipulation, high-velocity low-amplitude techniques, balanced ligamentous tension, muscle energy, strain-counter strain and soft tissue techniques) and these improved pain intensity, quality of life and perception of change after treatment [65]. It should be noted that our study demonstrates that, with a simpler protocol, significant changes can be achieved and on similar variables. Therefore, the combined approach proposed in the present study for the treatment of dysmenorrhea and the associated chronic pain offers a simple, and at the same time complete, perspective, and is a more effective tactic for clinicians.

4.1. Strengths and limitations of the study

As far as we know, this is the first study that combines body awareness sessions with OMT interventions for the treatment of dysmenorrhea. It is also worth highlighting the importance of studying treatment options for women with dysmenorrhea, a prevalent yet not broadly researched population of interest. Also, the selected interventions (non-pharmaceutical) can offer a valid option for health professionals.

Like all research, this study has some limitations. Since the sample was small, future studies with more robust samples should be conducted to corroborate the findings. Another limitation could be that no condition-specific measurements were applied. However, as this protocol has since shown positive results, it can be a starting point for future studies to apply and focus on other more specific variables. Finally, this study was conducted on women recruited from a specific geographical area, and therefore any future generalizations of its results must be limited to people with similar characteristics.

5. Conclusion

The combination of an osteopathic manual therapy protocol compared with body awareness significantly reduced the pain intensity and perception of pain in women with primary dysmenorrhea. Moreover, it improved quality of life, body satisfaction and global self-perception, as well as perceived change after treatment for the group that underwent the combined treatment. These results must be taken with caution, since the results reflect a short-term effect in people who experience chronic cyclical pain. Further, further studies should be conducted to verify the strength of our data. However, women suffering from dysmenorrhea and the health professionals who treat them may wish to consider the benefits that these treatment options can offer.

CRediT authorship contribution statement

María Conesa-Albaladejo: Writing – original draft, Software, Methodology, Investigation, Data curation, Conceptualization. **Gemma Victoria Espí-López:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Conceptualization. **Eva Martínez-Graullera:** Writing – original draft, Software, Resources. **Anna Arnal-Gómez:** Writing – review & editing, Writing – original draft, Software, Investigation.

Data availability statement

Data are available under reasonable request.

Ethical Approval

Ethical approval was granted by the Ethics Committee of the University of Valencia under protocol number H1512324924513.

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Declaration of competing interest

None declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijosm.2025.100761.

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