



RESEARCH REPORT

# Osteopathic treatment in patients with primary dysmenorrhoea: A randomised controlled trial



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## KEYWORDS

Osteopathy;  
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dysmenorrhoea;  
Randomised controlled  
trial;  
Clinical study

**Abstract Objectives:** To investigate the effectiveness of a series of osteopathic treatments in patients with pain due to primary dysmenorrhoea.

**Design and settings:** Multi-centered randomised controlled trial with an osteopathic intervention group and an untreated (“waiting list”) control group.

**Subjects:** Women aged 14 years and older with a regular menstrual cycle, diagnosed with primary dysmenorrhoea.

**Intervention:** Six osteopathic treatments over a period of three menstrual cycles or no osteopathic treatment. At each treatment session, dysfunctional structures were tested and treated based on osteopathic principles. In both groups, pain medication on demand was allowed, but was documented.

**Outcome measures:** Primary outcome measures were average pain intensity (API) during menstruation, assessed by the Numeric Rating Scale (NRS), and days of dysmenorrhoeal pain exceeding 50% of NRS maximum (DDP). Main secondary outcome measure was health-related quality of life.

**Results:** A total of 60 individuals (average age 33 years) were randomised, seven patients dropped out. API decreased in the intervention group from 4.6 to 1.9 (95%CI = -1.9 to -3.5), and from 4.3 to 4.2 in controls (95%CI = -0.7 to 0.5); between group difference of means (BGDoM): 2.6, 95%CI = 1.7 to 3.6;  $p < 0.005$ . DDP decreased from 2.2 to 0.2 days in the intervention group (95%CI = -2.5 to -1.3), and from 2.3 to 1.9 in controls (95%CI = -1.0 to 0.2); BGDoM 1.5; 95%CI = 0.6 to

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2.3;  $p = 0.002$ . A positive impact on quality of life (physical component score) could be observed in the osteopathic treatment group only.

*Conclusions:* A series of osteopathic treatments might be beneficial for women suffering from primary dysmenorrhoea.

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### Implications for practice

- No research published to date on this topic.
- Will help inform patients and clinicians.
- Helps facilitate and improve more research in the area.

## Introduction

Primary dysmenorrhoea refers to painful menstrual periods in the absence of any underlying pathology while secondary dysmenorrhoea is painful menstruation associated with a pelvic pathology, such as endometriosis.<sup>1</sup> Dysmenorrhoea is a very common problem among young women, and can occur in up to 50% of menstruating women.<sup>2,3</sup> Several studies suggest that severe menstrual pain is associated with absence from school or work and restricts other activities of daily life.<sup>4–6</sup> Primary dysmenorrhoea is commonly managed by three approaches: pharmacological, non-pharmacological and surgical. Simple analgesics are commonly used by young women, with use of analgesics reported by 52% of adolescents, and use of non-steroidal anti-inflammatory drugs (NSAIDs) reported by 42% of adolescents to alleviate their dysmenorrhoea.<sup>7</sup> Evidence of efficacy supports use of pharmacological agents such as NSAIDs<sup>8</sup> or the use of oral contraceptives<sup>9</sup> to alleviate menstrual pain from primary dysmenorrhoea, however pain relief may be inadequate for some women, or side effects may not be well tolerated.<sup>9,10</sup> Therefore, investigation of therapeutic alternatives is warranted. Manual therapies, including osteopathic treatment are commonly used to treat primary dysmenorrhoea despite the virtual absence of scientific evidence to support claims of pain reduction in women with this condition. However, reports of the efficacy/effectiveness of these therapeutic modalities are largely anecdotal and almost exclusively confined to the chiropractic literature.<sup>11–15</sup> Osteopathic treatment has been shown to be effective in the treatment of pain conditions like neck pain<sup>16,17</sup> or low back pain.<sup>18–20</sup> In an initial experimental effort into the

therapeutic potential of osteopathic treatment of primary dysmenorrhoea, the present study was designed to investigate the perceived effectiveness of osteopathic treatment of patients with pain due to primary dysmenorrhoea.

## Materials and methods

### Design

The present study was planned as a pragmatic multicenter randomised controlled trial. Patients who were enrolled into the study were allocated to an osteopathic intervention group that received osteopathic treatment during three menstrual cycles or to a control group that received no treatment during this period, but received osteopathic treatment afterwards (“waiting list design”). At the time the present study was performed, “official” ethics committees had been installed by the medical faculties of the German universities and the medical associations of the German federal states only. These bodies accepted only protocols of studies planned and carried out by physicians. However, the approval for the study protocol of this study was obtained from the German Academy of Osteopathy (AFO) following the rules of a German Institutional Review Board (IRB). The present study was conducted according to the standards of the Declaration of Helsinki and “Good Clinical Practice” guidelines.<sup>21</sup> All study participants provided written, informed consent.

### Participants

Participants were recruited from the general female population in Germany between 2005 and

2007 via word of mouth, flyers displayed in surgeries, advertisements in regional newspapers, and clinics and pharmacies. Telephone screenings of interested candidates were performed to establish potential eligibility for inclusion in the study.

Female patients could be included if they were aged 14 years and older, had a regular menstrual cycle ( $\pm 10$  days), and who were diagnosed with primary dysmenorrhoea by their general practitioner or gynaecologist. Patients were excluded if they used contraceptives, were pregnant, declared misuse of alcohol, drugs or medication, were treated for their pain by hormonal therapy, had illnesses that make medical treatment necessary and hence could influence the menstrual cycle, showed neurological conditions (e.g. treatment with steroids and opiates), or were diagnosed with secondary dysmenorrhoea.

Patients were randomly allocated to two groups: an intervention group that was treated osteopathically, and a control group, which was untreated during the study period. An external institution performed the assignment to the groups and documented the process in a standardised way. A computer generated randomisation list with a block length of six (block length not revealed to any party involved in the trial) was applied for each therapist. Participants were assigned to the respective groups once their date of birth and initials had been conveyed by telephone.

Patients in both groups completed in total four sets of assessments (before and during menstruation at cycles one to four), comprising of pain scales, use of medication and quality of life questionnaires.

## Interventions

The current study was conducted by three osteopaths who were also registered German naturopaths, having successfully completed five years of osteopathic training (approximately 1350 h) and passed a final clinical competence exam (reflecting the highest possible standard of osteopathic training in Germany). In order to facilitate consistent protocol implementation including the documentation of clinical findings and treatment procedures, and to minimise procedural variation, a trial-specific training session was organised before the beginning of the practical work. A standardised examination form was used by all three practitioners. Patients in the osteopathic intervention group received six treatment sessions delivered twice per cycle over a course of three

menstrual cycles. At each osteopathic treatment session, only those structures were treated for which osteopathic dysfunctions were present (not restricted to the abdominal and/or pelvic area). The techniques appropriate for each individual patient and therapeutic session were chosen by the osteopaths according to their findings, and were documented in detail. The osteopathic techniques could be applied if they could be considered "standard techniques in German osteopathic practices" and e.g. commonly referred to in the osteopathic literature,<sup>22</sup> including direct techniques (High Velocity Thrust, Muscle Energy Technique, myofascial release), indirect techniques (functional techniques, Balanced Ligamentous Tension) and visceral and/or cranial techniques.

At the first consultation, inclusion and exclusion criteria were recorded and eligible patients were randomised into one of the two groups after having received comprehensive information about the study and signing a consent form. With onset of the first menstruation after randomisation, the pain scales and all other questionnaires were completed, and patients received a medication diary, and the patients' medical history was taken. Patients in the osteopathic intervention group received a full osteopathic examination and treatment. Patients in the intervention group completed two further pain scales and medication questionnaires with onset of subsequent menstruations. At each of the five subsequent therapeutic sessions, patients were examined and received their treatment. Identified dysfunctions and osteopathic techniques applied were documented using a standardised form. Patients completed the final set of questionnaires at the end of their menstruation of the fourth menstrual cycle and sent them to their osteopath. For patients in the control group, outcome data were documented during each menstrual cycle and sent to the osteopath by post.

In both groups NSAID pain medication was allowed on demand (and was documented in a diary). Participants were asked not to seek other complementary treatment approaches while participating in the trial.

## Primary outcome measures

The average pain intensity during menstruation was assessed by means of a numeric rating scale (NRS) ranging from 0 = no pain at all to 10 = worst pain imaginable. The NRS is a widely used, short, easy to administer and validated measure of pain intensity in populations with pain.<sup>23</sup>

Duration of dysmenorrhoeal pain was determined by recording the number of days with dysmenorrhoeal pain in general and days with moderate to severe pain which was defined as of  $\geq 5$  on the NRS. This cut-off point was chosen based on previously published studies of chronic pain patients with different conditions, reporting 4 or 5 being the most commonly recommended lower limits for moderate pain and 7 or 8 for severe pain.<sup>24–28</sup>

## Secondary outcome measures

Duration of associated pains during menstruation, such as headaches, back pain, and general musculo-skeletal pain, was recorded regardless of localisation and intensity.

Duration and average intensity of bleeding over the course of the menstruation was assessed by recording number of days of bleeding and intensity by means of a Likert scale (1 = very strong bleeding, 5 = no bleeding).

Health-related quality of life was assessed by the generic SF-36 questionnaire which has been validated in German and for which standard values are available.<sup>29</sup>

Average intake of NSAIDs during the study period was recorded by dosage of medication used.

## Statistics

According to common standards in clinical trials, type I error was set at .05, and type II error at .2 (i.e. a power of 80%). Pain intensity on a numeric rating scale ranging from 0 to 10 points was used to determine the sample size. The trial was designed to be able to detect an (clinically meaningful) overall difference in changes of 1.5 points with assumed

standard deviations of 2.0 points (representing an effect size of .75). The sample size calculation estimated that 56 subjects would be required. We decided to aim at including 60 subjects.

Results of the descriptive analysis at baseline are reported as means and standard deviations. Differences between groups at baseline were examined using unpaired two-sided *t*-tests. For the confirmatory analysis, longitudinal changes of the different aspects of the primary outcome measure pain (quantified by NRS) during the course of treatment (i.e. between baseline and end of treatment) in both groups were compared by *t*-test (unpaired, two-sided). All patients with valid data were included in the analysis (per protocol analysis).

## Results

A total of 60 women with pain due to primary dysmenorrhoea fulfilled all inclusion and none of the exclusion criteria, and were randomised into either the osteopathic treatment group ( $n = 29$ ) or the control group ( $n = 31$ ). Seven participants discontinued with the study, four in the intervention group and three in the control group. Reasons for dropout were pregnancy (1), moving house (1), hospitalisation (1), no bleeding (1), other illness (1), hormone therapy (1) and magnet field therapy (1). Hence, final outcome data were available for 25 patients in the intervention group and 28 patients in the control group (Fig. 1).

## Baseline data

The baseline data had been collected during the last menstrual cycle before the beginning of the

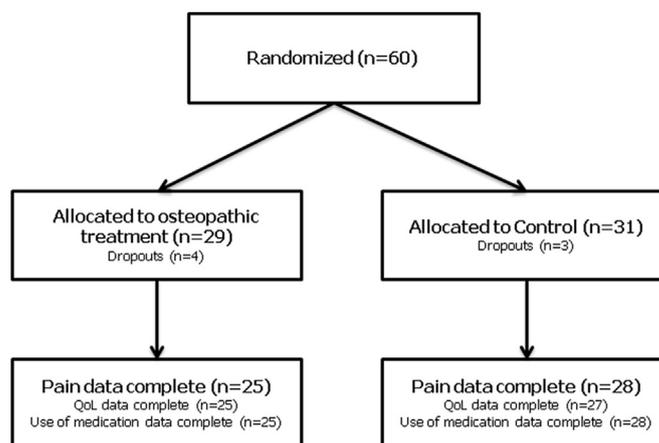


Fig. 1 Trial Flow chart. Abbrev: QoL – Quality of life.

**Table 1** Baseline characteristics of the study population.

Characteristic	Intervention group Mean (SD); <i>n</i> = 25	Control group Mean (SD); <i>n</i> = 28	<i>p</i> - Value
Age (years)	31.8 (13.2)	34.9 (7.9)	0.293
<b>Primary Outcome measures</b>			
Pain intensity [NRS]	4.6 (1.2)	4.3 (1.7)	0.501
Duration of dysmenorrhoeal pain [days]	4.5 (1.8)	4.6 (2.0)	0.873
Duration of dysmenorrhoeal pain ( $\geq 5$ on NRS) [days]	2.2 (1.4)	2.3 (2.2)	0.754
<b>Secondary Outcome measures</b>			
Duration of associated pains [days]	5.2 (1.8)	5.3 (2.4)	0.861
Duration of bleeding [days]	5.3 (1.0)	5.6 (1.5)	0.313
Intensity of bleeding [Likert]	3.0 (0.6)	2.9 (0.5)	0.333
SF-36 PCS	44.2 (9.5)	49.1 (9.5) ( <i>n</i> = 27)	0.071
SF-36 MCS	45.5 (9.7)	42.0 (12.3) ( <i>n</i> = 27)	0.256

Abbrev: NRS – Numeric rating Scale (0 = no Pain; 10 = worst imaginable Pain); SD – Standard deviation; Likert scale (1 = very strong bleeding, 2 = strong bleeding, 3 = normal bleeding, 4 = weak bleeding, 5 = no bleeding); PCS – Physical Component Score; MCS – Mental Component Score.

treatment period. With regard to age and presenting complaints, there were no significant differences between the two groups. For the QoL questionnaire, the number of participants reduced

to 27 in the control group because one patient did not fill in her SF-36 questionnaire. The baseline data of those patients who discontinued within the study were not further assessed. The baseline characteristics of both groups are shown in Table 1, indicating that randomisation was successful and that both groups were comparable.

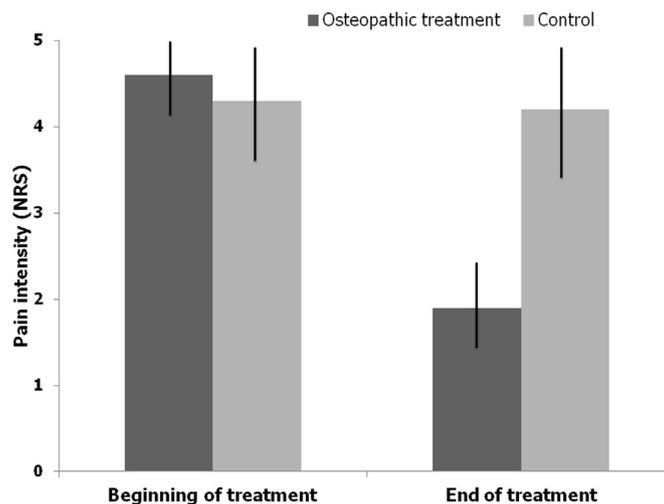
### Intensity and duration of dysmenorrhoeal pain

Pain intensity decreased from 4.6 to 1.9 on the NRS in the osteopathic intervention group and from 4.2 to 4.1 in the control group (mean difference of changes 2.6, 95%CI 1.7 to 3.6,  $p < .0005$ ) (Fig. 2), duration of pain decreased in the osteopathic treatment group from 4.5 to 2.2 days, and increased from 4.6 to 4.8 days in the control group (mean difference of changes 2.5 days, 95%CI 1.6 to 3.5 days,  $p < .0005$ ), and number of days with pain  $\geq 5$  on the NRS decreased from 2.2 to 0.2 days in the osteopathic treatment group and from 2.3 to 1.9 days in the control group (mean difference of changes 1.5 days, 95%CI 0.6 to 2.3 days,  $p = .002$ ). Details are presented in Tables 2a and 2b including an analysis of within-group changes.

Effect sizes were  $d = 1.49$  for pain intensity and  $d = 0.94$  for duration of pain ( $\geq 5$  on NRS), respectively.

### Health-related quality of life

In the quality of life assessment the mean physical component score of the SF-36 changed from 44.2 to 49.9 in the osteopathic treatment group and from 49.1 to 48.8 in the control group (mean



**Fig. 2** Intensity of dysmenorrhoeal pain before and after the treatment period. Abbrev: NRS – Numeric rating Scale (0 = no Pain; 10 = worst imaginable Pain); Error bars indicate 95% Confidence intervals.

**Table 2a** Between-group differences of changes of intensity and duration of dysmenorrhoeal pain between baseline and end of treatment.

	Longitudinal changes Baseline – end of treatment		Difference of longitudinal changes [95% CI]	p-Value
	Osteopathic group (n = 25) mean ± SD	Control group (n = 28) mean ± SD		
Pain intensity [NRS]	-2.7 ± 1.9	-0.1 ± 1.6	2.6 [1.7–3.6]	<0.0005
Duration of pain [days]	-2.3 ± 2.1	0.2 ± 1.4	2.5 [1.6–3.5]	<0.0005
Duration of pain (≥5 on NRS) [days]	-1.9 ± 1.6	-0.4 ± 1.6	1.5 [0.6–2.3]	0.002

Abbrev: SD – Standard deviation; NRS – Numeric rating Scale (0 = no Pain; 10 = worst imaginable Pain); CI – Confidence Interval.

difference of changes 6.2, 95%CI 1.2 to 11.1,  $p = .015$ ), the mean mental component score changed from 45.5 to 45.9 in the osteopathic treatment group and from 42.0 to 44.4 in the control group (mean difference of changes 2.0, 95%CI -2.6 to 6.7,  $p = .39$ ) (Tables 3a and 3b).

### Use of medication

Nine women in the osteopathic treatment group and 11 women in the control group used NSAIDs to alleviate their pain during the study period. The average use of NSAIDs decreased in the osteopathic intervention group by 75% from 2000 mg at the first cycle to 480 mg at the last cycle of the study period. In comparison, the control group reported a moderate increase in the use of pain medication from 1400 mg to 1800 mg.

### Adverse events

No adverse events or adverse reactions were reported during the treatment period.

### Associated pains and bleeding

Improvements were noted in both groups in the duration of associated pains, independent of

localisation, intensity and diversity of complications with the osteopathic intervention group showing a more marked improvement compared with the control group. In contrast, duration and intensity of bleeding did not change in both groups during the treatment period and there was also no significant difference in changes between groups in the number of days with bleeding and intensity of bleeding.

### Osteopathic examination patterns

The most frequent osteopathic dysfunctions were observed in the area of the pelvic floor (100% of patients) and respiratory diaphragm (92% of patients) as well as within the lumbar spine (80% of patients) and the association of the bones of the head (76% of patients).

### Discussion

This study aimed to examine the effectiveness of a series of osteopathic treatments compared to “no intervention” concerning pain intensity and pain duration in women with primary dysmenorrhoea. To our knowledge, this is the first study to show that patients seeking help from an osteopath for

**Table 2b** Within-group changes of intensity and duration of dysmenorrhoeal pain between baseline and end of treatment.

	Baseline Mean ± SD	End of treatment Mean ± SD	Difference of longitudinal changes [95% CI]	p Value
Pain intensity [NRS]				
- osteopathic group	4.6 ± 1.2	1.9 ± 1.4	-2.7 [-3.5 to -1.9]	<0.0005
- control group	4.3 ± 1.7	4.2 ± 1.8	-0.1 [-0.7 to 0.5]	0.735
Duration of pain [days]				
- osteopathic group	4.5 ± 1.8	2.2 ± 1.8	-2.3 [-3.2 to -1.5]	<0.0005
- control group	4.6 ± 2.0	4.8 ± 2.0	0.2 [-0.3 to 0.7]	0.494
Duration of pain (≥5 on NRS) [days]				
- osteopathic group	2.2 ± 1.4	0.2 ± 0.6	-1.9 [-2.5 to -1.3]	<0.0005
- control group	2.3 ± 2.2	1.9 ± 1.9	-0.4 [-1.0 to 0.2]	0.141

Abbrev: SD – Standard deviation; NRS – Numeric rating Scale (0 = no Pain; 10 = worst imaginable Pain); CI – Confidence Interval.

**Table 3a** Between-group differences of changes of Quality of life (SF-36) sum scores between baseline and end of treatment.

	Longitudinal changes Baseline – end of treatment		Difference of longitudinal changes [95% CI]	p-Value
	Osteopathic group (n = 25) mean ± SD	Control group (n = 27) mean ± SD		
SF-36 PCS	5.7 ± 8.5	−0.5 ± 9.2	6.2 [1.2 to 11.1]	0.015
SF-36 MCS	0.4 ± 9.0	2.4 ± 7.8	2.0 [−2.6 to 6.7]	0.390

Abbrev: SD – Standard deviation; CI – Confidence Interval; PCS – Physical Component Score; MCS – Mental Component Score.

this problem may observe relevant improvements in pain intensity, pain duration and quality of life compared to women who seek help but receive no osteopathic treatment.

Participating women reported an average pain intensity of 4.6 on a numeric rating scale at baseline, and pain intensity was reported to be in excess of 5.0 on the NRS for over two days per cycle. This can be considered a significant level of pain, and participants which were typically in their early thirties may look at another 15 or so years with two days of relevant pain every month – with no relevant treatment likely beyond pain killers. Although we did not evaluate this aspect in detail, one can assume that most participants had tried a variety of treatment modalities unsuccessfully over 10 or more years on average. Against this background, perceived (short term) effectiveness of the osteopathic treatment, i.e. a reduction in pain intensity in a dimension of 60% and a virtual disappearance of pain levels exceeding 5 on an NRS can be considered a promising first piece of evidence for a non-invasive, non-drug intervention that may warrant further investigation.

So far, studies into primary dysmenorrhoea and manual therapies have focused mainly on spinal manipulation as a form of treatment. The most recently published systematic reviews on the effects of spinal manipulation in women with

dysmenorrhoea found no evidence that spinal manipulation is effective in the treatment of this condition.<sup>30,31</sup>

The present trial was designed to reflect the real life situation of women suffering from primary dysmenorrhoea in Germany. In general, patients do not receive any specific treatment beyond advice to take pain medication on demand. This may to some extent reflect the presumption that dysmenorrhoeal problems are decreasing in severity with age and childbirth.<sup>32–35</sup> Complementary treatment options such as osteopathic treatment are generally sought only on the women's own initiative, and treatment costs are not normally reimbursed by the statutory health insurance in Germany.

Thus, this study aimed to test the “value of seeking help from an osteopath” (i.e. the perceived effectiveness rather than the efficacy of particular osteopathic techniques), a pragmatic approach<sup>36</sup> reflecting the real life situation of deliberately seeking treatment from an osteopath for primary dysmenorrhoeal symptoms. Results may thus have significant external validity.<sup>37,38</sup>

Also, for the patients in the control group participation was not associated with any disadvantage compared to their normal situation while they were on the waiting list with the perspective of the potential benefit of an osteopathic treatment thereafter.

**Table 3b** Within-group changes of Quality of life (SF-36) sum scores within groups between baseline and end of treatment.

	Baseline	End of treatment	Difference of longitudinal changes [95% CI]	p Value
SF-36 PCS				
- osteopathic group	44.2 ± 9.5	49.9 ± 6.5	5.7 [2.2 to 9.2]	0.003
- control group	49.1 ± 9.5	48.6 ± 8.8	−0.5 [−4.1 to 3.1]	0.786
SF-36 MCS				
- osteopathic group	45.5 ± 9.7	45.9 ± 9.1	0.4 [−3.3 to 4.1]	0.839
- control group	42.0 ± 12.3	44.4 ± 11.8	2.4 [−0.7 to 5.5]	0.123

Abbrev: SD – Standard deviation; CI – Confidence Interval; PCS – Physical Component Score; MCS – Mental Component Score.

The treatment regimens of patients in our study were intentionally not standardised, because we intended to depict the real life situation on one hand, and did not want to compromise the potential effect of an "optimal" osteopathic intervention by standardising the intervention in a way that would be conflicting with fundamental treatment principles of osteopathy.

The framework of the trial with on demand medication as the true control condition is also in keeping with the concept of CER (comparative effectiveness research), an increasingly vigorously advocated new rationale for clinical trials (for details refer to the Federal Coordinating Council for Comparative Effectiveness<sup>39</sup>). Not least, the present trial would not preclude trials with a focus on particular aspects of cause and effect and/or potential modes of action, and may lead the way to formulate further sensible hypotheses, provided it turns out to show a potentially meaningful superiority of the osteopathic treatment over "current standards".<sup>40</sup>

Explanatory trials (i.e. trials focusing on the efficacy of an intervention) consistently apply an intention to treat analysis to test respective hypotheses, thereby maximising internal validity of the trial (from a methodological point of view at the expense of the external validity of a trial). Since this trial aimed at studying the effects of an "osteopathic treatment that had a chance to work", a per protocol analysis had been considered as the most appropriate statistical procedure. We therefore included only those patients who had been receiving the treatment as planned. Given that only four women in the intervention group and three women in the control group dropped out, the per protocol analysis is unlikely to have significantly biased the results (i.e. compromised internal validity), furthermore, the reasons for dropout were evaluated in all cases and were, in most instances, unlikely to be associated with the treatment.

Clinical trials concerned with manual therapy or other interventions directly delivered by a therapeutically skilled person are prone to bias if there is just one person to deliver the therapy. In order to test the treatment approach and not the therapist, three well-trained and experienced osteopaths performed the treatments.

This study also produced, to our knowledge for the first time, some experimental evidence on potentially particularly useful techniques in this context that may be considered in future trials. This adds to the knowledge in this area as, until now, only consensus based on personal empirical evidence has been available to guide treatment.

There are various limitations inherently associated with trials applying a waiting list design. Participants are aware of whether they are receiving treatment or are awaiting treatment. This may trigger non-specific effects as, for instance, expectation, which must be assumed to have been present in the intervention group, and absent in the control group. The lack of blinding allows for a personal "therapeutic relationship" to be established between patient and therapist, and a "positive therapeutic environment" may be supportive in terms of trust and confidence. The above reasoning implies that the waiting list design does not allow differentiation between specific and different non-specific components of an overall (perceived) treatment effect, but it can still give valid information concerning the reliability (reproducibility) of the extent of change associated with the decision to seek and receive help from an osteopath.

We are unable to report quantitative data on some aspects of the patient recruitment process, as, for instance, on the ratio of patients eligible and patients enrolled. Bearing in mind the heterogeneity of strategies applied to approach women potentially interested in participation (e.g. word of mouth, newspapers, co-operating gynaecologists etc.), and the number of cases planned to be included we did not expect to be able to derive reliable information on potentially relevant predictors such as personal background, history of the condition, or personal preferences. Therefore the protocol of this pragmatic trial gave other aspects higher priority.

At the planning stage, we felt that if patients completed outcome questionnaires at home, they may not feel urged to positively overestimate their ratings. However, we cannot exclude that this may have influenced ratings in one way or another. In the meantime we would favour a procedure that assures a higher level of confidentiality such as postal return to a neutral third party, with the ratings undisclosed to therapists.

Another limitation of the waiting list design is that it does not allow performing follow ups, because after the end of the treatment period of the intervention group the control group is being offered treatment, thus converting the former control group into an intervention group, too. One might argue, however, that performing a follow up may be worth the effort only if reasonable treatment effects to follow up have been observed at the end of the treatment period.

Taken together, the present study assessed the perceived effect of a series of osteopathic treatments. Assessing the overall effect rather than

parts of it seems to be a sensible first step. In case there is preliminary positive evidence, further studies focusing on potentially relevant components may be undertaken. If a first study focuses on the wrong component, however, the consequence may be no further research activities concerning the problem.

## Conclusions

In conclusion, our study is the first to provide evidence that a series of five osteopathic treatments over a period of three cycles might be beneficial for women suffering from primary dysmenorrhoea. Further studies might focus on particular components of the overall effect observed in this study, and will have to demonstrate whether long-term outcomes can be achieved.

## Author contribution statement

FS, PW, MR contributed to the design and planning of the research. PW and MR were involved in the data collection and analysis of results. FS and KLR drafted the manuscript. All authors were involved in the critical revision of the manuscript.

## Author disclosure statement

The authors have no conflict of interest.

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