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CLINICAL PAPER

Homeopathic treatment of premenstrual syndrome: a case series

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Objective: **Observational, prospective study to describe the homeopathic management of premenstrual syndrome (PMS) by a group of French physicians.**
Method: **Women with PMS for >3 months were prescribed individualized homeopathic treatment. The intensity of 10 clinical symptoms of PMS was scored individually at inclusion and at a 3–6 month follow-up visit: absent = 0, mild = 1, moderate = 2, severe = 3. Total symptom score (range: 0–30) was calculated and compared for each patient at inclusion and at follow-up. PMS impact on daily activities (quality of life, QoL) was compared at inclusion and follow-up as: none, mild, moderate, severe, very severe.**
Results: **Twenty-three women were prescribed homeopathic treatment only (mean age: 39.7 years). *Folliculinum* (87%) was the most frequently prescribed homeopathic medicine followed by *Lachesis mutus* (52.2%). The most common PMS symptoms (moderate or severe) at inclusion were: irritability, aggression and tension (87%), mastodynia (78.2%) and weight gain and abdominal bloating (73.9%); and the most common symptoms at follow-up were: irritability, aggression and tension (39.1%), weight gain and abdominal bloating (26.1%) and mastodynia (17.4%). Mean global score for symptom intensity was 13.7 at inclusion and 6.3 at follow-up. The mean decrease in score (7.4) was statistically significant ($p < 0.0001$). Twenty-one women reported that their QoL also improved significantly (91.3%; $p < 0.0001$).**
Conclusions: **Homeopathic treatment was well tolerated and seemed to have a positive impact on PMS symptoms. *Folliculinum* was the most frequent homeopathic medicine prescribed. There appears to be scope for a properly designed, randomized, placebo-controlled trial to investigate the efficacy of individual homeopathic medicines in PMS.**
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Keywords: Homeopathy; Observational study; Premenstrual syndrome; *Folliculinum*; Women's health; Symptoms management

Introduction

Premenstrual syndrome (PMS) is a common condition, affecting 3–5% of women of childbearing age,[1] and encompasses a broad range of somatic, mood and behavioural symptoms that appear during the luteal phase of the menstrual cycle (MC) and disappear when menstruation begins. Numerous symptoms have been described in daily diary recordings of patients and several symptom-based tools for the diagnosis of PMS and the more severe form of the condition, known as premenstrual dysphoric disorder (PMDD), have been proposed.[2–7] The social burden of PMS is high and the repeated cyclic nature of symptoms can cause significant impairments in personal/family relationships and everyday life[8].

Symptoms of PMS are severe enough to warrant treatment in 20–25% of women.[9] Treatment strategies are based on either suppression of the hormonal cycle leading to ovulation or treatment of individual symptoms that cause the most distress to patients.[10] The systematic review of the Cochrane Database 2009 by Brown *et al.*[1] supports the efficacy of selective serotonin reuptake inhibitors in patients with severe PMS, and a second review of the Cochrane Database 2009 by Lopez *et al.* showed possible efficacy of combined oral

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contraceptives containing drospirenone (plus ethinyl estradiol 20 μg).[11] However, side-effects including nausea, insomnia, intermenstrual bleeding, asthenia, breast pain and decreased libido have been reported with these treatments and often result in treatment withdrawal.[1,11]

Many women are now turning to therapies outside of conventional medicine such as homeopathy, acupuncture and cognitive-behavioural therapy in order to relieve their PMS symptoms.[12] Several recent studies and literature reviews report the efficacy of a number of herbal, vitamin, fatty acid and mineral-based remedies in women with PMS.[12–16]

We carried out this observational study in women with PMS in order to describe the homeopathic management of PMS by a group of general practitioners (GPs) and gynaecologists with experience in homeopathy and to assess the effect of homeopathic treatments in relieving PMS symptoms and improving quality of life (QoL).

Materials and methods

This prospective, observational study was carried out between September 2008 and April 2010 in seven centres in France. Seven GPs and gynaecologists with experience and expertise in prescribing homeopathic medicines participated in the study. These doctors had all received specific training in homeopathy during their Masters degree.

Patients

Physicians recruited the first women who presented at their surgery for the main reason of PMS, with symptoms present for >3 months, and if they were prescribed homeopathic treatment at the time of consultation. In these cases, the study was proposed to the women and if they agreed to participate the physicians completed the study documents according to the oral declarations made by the women concerning symptoms and QoL. No specific criteria were used for the diagnosis of PMS as it was an observational study based on the procedures used in daily clinical practice; the clinical symptoms of PMS were not prompted by the physician and the diagnosis was made by the physicians solely on the basis of the symptoms declared spontaneously by the patients. Thus, the symptoms reported by the women were not prompted by the clinical diagnosis established by the physician. The diagnosis depended on the competence of the physician to identify PMS.

Women were not included in the study if they had: any known neoplastic gynaecological pathology, hysterectomy, continuous progestative treatment (implant, vaginal ring, intrauterine device, pill) or combined oral contraceptives (oestrogen and a progestogen). Women were also excluded if they did not comply with treatment, if there was a change in their hormone status (introduction of an oestrogen and/or progestogen, amenorrhoea, pregnancy), if they underwent a hysterectomy and/or bilateral oophorectomy during the study period, or if they withdrew consent or were lost to follow-up.

All patients were required to attend an inclusion consultation and a follow-up consultation, usually between 3 and 6 months later. All women gave their informed consent to participate. Physicians were remunerated for participation in the study, but no patient received any payment or other incentive.

Therapy

All women were prescribed homeopathic medication by their physician (GP or gynaecologist) who recorded the treatment prescribed on the study documents. The choice of treatment, dosage and treatment duration were left to the discretion of the treating physician and were individualized for each patient.

Assessment of clinical progress

All patients were followed for a period of 3–6 months after initiation of treatment. As mentioned above, the intensity of symptoms and impact of PMS on QoL were recorded by the physicians according to oral declarations made by the women at inclusion and at the follow-up visit. The intensity of 10 clinical symptoms of PMS (mastodynia; irritability – aggression – tension; feeling depressed; asthenia; weight gain and abdominal bloating; feeling of bearing down; heaviness of lower limbs; back pain; headaches; skin manifestations) was scored individually at inclusion and at follow-up, as follows: symptom absent = 0, mild in intensity = 1, moderate in intensity = 2, severe in intensity = 3. The global score for the 10 symptoms was then determined by adding up the individual scores to give a final score ranging from 0 to 30. The global symptom score was then compared for each patient at inclusion and at the 3–6 month follow-up. Evolution of symptom intensity was rated as: aggravation (change from absent to mild, mild to moderate, moderate to severe); stable (no change); or improvement (change in intensity from severe to moderate, moderate to mild or mild to absent).

The impact of PMS symptoms on daily activities was assessed by the women as: none, mild, moderate, severe, very severe. Evolution of impact on daily activities was rated as: improvement (change from very severe to severe, severe to moderate, moderate to mild or mild to none); stable (no change); or aggravation (change from none to mild, mild to moderate, moderate to severe, or severe to very severe).

Statistical analysis

The following tests were used to compare the data collected at inclusion and at follow-up: Student's *t* test or Wilcoxon test (Shapiro–Wilk) for quantitative data, or generalized equations of estimation for qualitative data. Alpha risk was fixed at 5%. *p* Values were calculated using a GEE (generalized estimating equations) model.

All statistical analyses were carried out using SAS software.

Results

Study population

A total of 34 women with PMS were recruited during the study period. Five were excluded from the final analysis for the following reasons: wrongly included in the study

Table 1 Symptoms (moderate or severe) of PMS at inclusion, homeopathic medicines prescribed and impact of PMS on QoL

Patient	*Moderate or severe symptoms at inclusion*	*Medicaments prescribed*	*Formulation and dosage*†	*Treatment duration (months)*	*Follow-up (months)*	*QoL*	
						Distress at inclusion	*Distress at follow-up*
1 36 years	Mastodynia; irritability, aggression, tension, asthenia; weight gain and abdominal bloating, headaches; skin manifestations	*Folliculinum* 15c *Lycopodium clavatum* 9c *Nux vomica* 9/15/30c *Natrum muriaticum* 30c *Lachesis mutus* 15c	1 D on day 8 of the MC 3 GR/day from 16th day to end of MC 1 D on day 22, 23 and 24 of the MC 1 D every week 3 GR/day from 16th day to end of MC	6	7	Severe	None
2 29 years	Mastodynia; irritability, aggression, tension; asthenia; weight gain and abdominal bloating	*Folliculinum* 15c *Lycopodium clavatum* 5c *Lachesis mutus* 9/15/30c	1 D on day 8 of the MC 3 GR/day from 15th day to end of MC 1 D on day 20, 21 and 22 of the MC	6	6	Severe	Mild
3 37 years	Mastodynia; irritability, aggression, tension; asthenia, weight gain and abdominal bloating; skin manifestations	*Folliculinum* 15c *Lac caninum* 15c *Nux vomica* 15c *Pulsatilla* 9/15/30c	1 D on day 8 of the MC 1 D on day 15 of the MC 3 GR/day from 16th day to end of MC 1 D on day 20, 21 and 22 of the MC	6	7	Severe	Mild
4 36 years	Mastodynia; irritability, aggression, tension; asthenia; headaches; skin manifestations	*Folliculinum* 15c *Lac caninum* 15c *Lachesis mutus* 15c *Gelsemium* 9c *Cyclamen europaeum* 7c *Nux vomica* 15c	1 D on day 8 of the MC 3 GR/day from 15th day to end of MC 3 GR/day from 15th day to end of MC 3 GR/day from 20th day to end of MC 3 GR/day from 20th day to end of MC 1 D every week	4	5	Very severe	Moderate
5 50 years	Irritability, aggression, tension; asthenia; headaches	*Ignatia amara* 15c *Lachesis mutus* 15c *Gelsemium* 9c *Nux vomica* 15c *Coffea cruda* 9c	3 GR/day 3 GR twice a day 3 GR/day 3 GR/day 3 GR/day	6	9	Moderate	None
6 43 years	Mastodynia; weight gain and abdominal bloating; pelvic heaviness; heaviness of lower limbs (with or without oedema)	*Sepia officinalis* 30c *Folliculinum* 30c *Phytolacca decandra* 9c *Lac caninum* 15c *Lachesis mutus* 9c	1 D every week 1 D on day8 and day 22 of the MC 5 GR/day 5 GR/day 5 GR/day	4	3	Severe	Mild
7 19 years	Mastodynia; irritability, aggression, tension; weight gain and abdominal bloating; skin manifestations	*Folliculinum* 15c *Lac caninum* 5c *Lachesis mutus* 12c	1 D on day 8 and day 20 of the MC 5 GR from 20th day of MC 5 GR from 20th day of MC	3	2.5	Moderate	Mild
8 45 years	Irritability, aggression, tension; weight gain and abdominal bloating; pelvic heaviness; headaches	*Folliculinum* 9c *Lycopodium clavatum* 15c *Vipera redi* 9c *Natrum muriaticum* 12c	1 D on day 8 and day 20 of the MC 5 GR/day 5 GR/day 1 D every week	3	3	Severe	Mild
9 44 years	Irritability, aggression, tension; weight gain and abdominal bloating; pelvic heaviness	*Lachesis mutus* 15c *Stramonium* 30c *Vipera redi* 5c *Nux vomica* 12c	5 GR/day 5 GR/day 5 GR/day 1 D every week	3	3	Very severe	Moderate

(*Continued on next page*)

Table 1 *(continued)*

Patient	*Moderate or severe symptoms at inclusion*	*Medicaments prescribed*	*Formulation and dosage†*	*Treatment duration (months)*	*Follow-up (months)*	*QoL*	
						Distress at inclusion	*Distress at follow-up*
10 42 years	Mastodynia; irritability, aggression, tension; weight gain and abdominal bloating; heaviness of lower limbs (with or without oedema); back pain	*Folliculinum* 15c *Cedron* 15c *Histaminum* 9c	1 D on day 8 and day 20 of MC 1 D on 24th day of MC 1 D on 22nd day of MC	5	4	Mild	Moderate
11 48 years	Mastodynia; irritability, aggression, tension; depressive tendency; asthenia; weight gain and abdominal bloating; pelvic heaviness	*Folliculinum* 12c *Histaminum* 9c	1 D on day 14 of the MC 1 D on day 15 of the MC	4	3.5	Moderate	Mild
12 34 years	Mastodynia; irritability, aggression, tension; depressive tendency; asthenia; weight gain and abdominal bloating; pelvic heaviness; heaviness of lower limbs (with or without oedema); back pain; skin manifestations	*Folliculinum* 15c *Histaminum* 9c	1 D on day 8 and day 20 of the MC 1 D on 22nd day of MC	4	5.5	Severe	Mild
13 39 years	Mastodynia; pelvic heaviness; heaviness of lower limbs (with or without oedema); back pain	*Folliculinum* 9c	1 D on day 14 of the MC	4	3.5	Moderate	None
14 44 years	Mastodynia; irritability, aggression, tension; depressive tendency; asthenia; weight gain and abdominal bloating; pelvic heaviness; headaches	*Folliculinum* 15c *Tyraminum* 9c *Sepia officinalis* 15c	1 D on day 8 and day 20 of the MC 1 D on the 21st day of the MC 1 D on the 22nd day of the MC	4	3.5	Severe	Mild
15 52 years	Irritability, aggression, tension; asthenia; weight gain and abdominal bloating; pelvic heaviness; heaviness of lower limbs (with or without oedema); back pain	*Thuya occidentalis* 15c *Natrum sulfuricum* 15c *Lachesis mutus* 15c *LHRH* 15c	1 D per week 5 GR/day 5 GR/day 5 GR/day	MD	3.5	Severe	Moderate
16 33 years	Mastodynia; irritability, aggression, tension; depressive tendency; asthenia, heaviness of lower limbs (with or without oedema); headaches	*Folliculinum* 30c *Lachesis mutus* 9/15/30c *Sepia officinalis* 15c *Cyclamen europaeum* 9c	1 D on day 7 of the MC 1 D on 17th/18th/19th day of the MC 5 GR/day 5 GR/day	4	4	Severe	Moderate
17 47 years	Mastodynia; irritability, aggression, tension; weight gain and abdominal bloating; pelvic heaviness; headaches	*Folliculinum* 30c *Lachesis mutus* 9/15/30c *Cyclamen europaeum* 9c	1 D on day 7 of the MC 1 D on 17th/18th/19th day of the MC 5 GR	4	3	Moderate	Moderate
18 42 years	Mastodynia; irritability, aggression, tension; depressive tendency; weight gain and abdominal bloating; pelvic heaviness; headaches	*Folliculinum* 30c *Lachesis mutus* 9/15/30c	1 D on day 8 of the MC 1 D on 19th/20th/21st day of the MC	3	4	Severe	Mild

19 *34 years*	*Irritability, aggression, tension; depressive tendency; asthenia; weight gain and abdominal bloating; back pain*	Folliculinum *30c* Lachesis mutus *9/15/30c* Luteinum *5c*	*1 D on day 7 of the MC* *1 D on 18th/19th/20th day of the MC* *5 GR/day in the 2nd half of the MC*	*4*	*4.5*	*Very severe*	*Mild*
20 *22 years*	*Mastodynia; irritability, aggression, tension; weight gain and abdominal bloating*	Folliculinum *30c* Natrum muriaticum *30c*	*1 D per week* *1 D per week*	*3*	*3*	*Severe*	*Mild*
21 *49 years*	*Mastodynia; irritability, aggression, tension; depressive tendency; asthenia*	Folliculinum *30c* Progesteronum *15c*	*1 D per week* *1 D on the 21st day of the MC*	*6*	*4*	*Very severe*	*Moderate*
22 33 years	Mastodynia	*Folliculinum* 30c *Progesteronum* 15c	1 D on day 10 and day 20 of the MC 1 D on the 20th day of the MC	4	5	Severe	Mild
23 56 years	Mastodynia; irritability, aggression, tension; weight gain and abdominal bloating; pelvic heaviness; back pain	*Folliculinum* 30c *Gelsemium* 30c *Progesteronum* 15c	1 D per week 1 D on the 20th day of the MC 1 D on the 20th day of the MC	3	3	Severe	Moderate

D: dose; GR: granules.
†One dose consists of 200 globules and corresponds to approximately 10 granules.
MD: Missing Data

(receiving oestrogen and/or progestogen treatment), $n = 2$; premature withdrawal, $n = 1$; poor compliance, $n = 1$; lost to follow-up, $n = 1$. Six further patients were excluded since they did not receive homeopathic treatment exclusively. Thus, the final population analyzed consisted of 23 women (mean age 39.7 years, range: 19−56). The clinical symptoms of PMS in these women at inclusion are shown in Table 1.

Homeopathic medicines prescribed

The homeopathic treatments and dosages prescribed to the 23 women are summarized in Table 1. The most frequently prescribed homeopathic medicine was *Folliculinum* (20/23; 87%), mainly 15c and 30c, followed by *Lachesis mutus* 15c and 30c (12/23; 52.2%). One patient took *Folliculinum* only, six patients (26.1%) took two different medicines, 12 patients (52.2%) took three or four different medicines and four (17.4%) took five or six. *Folliculinum* was associated with *Lachesis mutus* in nine patients (39.1%), with *Lycopodium clavatum* in three (13.0%), with *Nux vomica* in three (13.0%), with *Lac caninum* in four (17.4%), with *Natrum muriaticum* in three (13.0%), with *Cyclamen europaeum* in three (13.0%), with *Histaminum* in three (13.0%) and with *Progesteronum* in three (13.0%). Prescription of *Folliculinum* was not associated with any particular symptom.

Concerning the dosage, *Folliculinum* is prescribed twice during the MC when oestrogen secretions are maximal: once before ovulation (around the 8th day of the MC) and then around the 20th day of the MC (oestrogenic peak). Other homeopathic medicines were also prescribed cyclically.

PMS symptoms at inclusion

The symptoms of PMS at inclusion are shown in Table 1. The most frequent clinical symptoms (moderate or severe) of PMS at inclusion were: irritability, aggression and tension in 20 (87%) women, mastodynia in 18 (78.2%) and weight gain and abdominal bloating in 17 (73.9%).

The mean global score for symptom intensity at inclusion was 13.7.

Effects of homeopathic treatment at follow-up

The most frequent clinical symptoms (moderate or severe) at follow-up were: irritability, aggression and tension in nine women (39.1%), weight gain and abdominal bloating in six (26.1%) and mastodynia in four (17.4%).

The mean global score for symptom intensity at follow-up was 6.3. The mean decrease in global score from inclusion (−7.4) was statistically significant ($p < 0.0001$). All patients reported an improvement in their symptoms at the end of the study, particularly irritability, aggression and tension, and mastodynia, which were the most common clinical symptoms at inclusion. The difference in results between inclusion and follow-up was statistically significant for all symptoms except back pain (Table 2).

QoL also improved significantly at follow-up in 21 of the 23 women (91.3%; $p < 0.0001$) (Figure 1). In the two women who did not report an improvement in QoL, the distress caused by PMS remained unchanged in one (patient 17) and had become worse in one (patient 10).

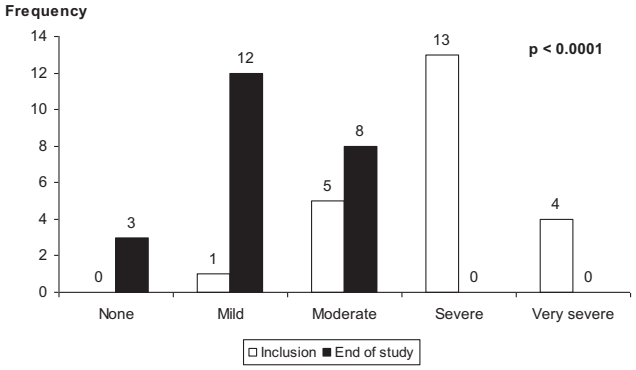

Figure 1 Change in QoL between inclusion and follow-up.

Mean follow-up time for the 23 patients was 19 weeks (131.0 ± 48.1 days), corresponding to five MCs. The minimum duration was 76 days (2.5 months), the median was 122 days and the maximum was 269 days (9 months).

Homeopathic treatment was well tolerated and compliance with treatment was good.

Discussion

The results of this study support those of previous randomized placebo-controlled trials (RCTs) where homeopathic medicines appeared to be effective at reducing PMS symptoms.[17,18] In the 23 women in our study, there was a significant decrease in intensity of all symptoms except back pain at the 3−6 month follow-up and 21 women (91.3%) reported that PMS was no longer a significant problem in their daily life.

The most frequently prescribed remedy was *Folliculinum*, mainly 15c and 30c, but also 9c, 7c and 12c. *Folliculinum* is a homeopathic medicament made from oestrone, a synthetic form of oestrogen. One of the physiological mechanisms proposed for PMS is a hormonal imbalance between oestrogen and progesterone.[19,20]

In the absence of official recommendations on the management of PMS there has been much interest in complementary therapies for the treatment of PMS symptoms over the past decade. Whelan *et al.* identified 62 herbs, vitamins and minerals for which claims of efficacy in PMS have been made.[13] However, only calcium appeared to have good quality evidence to support its use in PMS, while chasteberry and vitamin B6 may be effective.[13] Data in the literature also support the possible efficacy of polyunsaturated (essential) fatty acids in PMS.[14,16] *Hypericum perforatum* has been shown to improve the physical and behavioural symptoms of PMS but has no effect on mood- and pain-related symptoms compared to placebo.[15] In an RCT carried out in France in 1995, Lapaisant reported that *Folliculinum* was more effective at reducing mastodynia in women with PMS than placebo.[17] The efficacy of homeopathic treatment at reducing the symptoms of PMS was confirmed in another placebo-controlled RCT carried out in Israel by Yakir *et al.*[18]

Most studies performed to date are not RCTs and do not measure the effect of treatment on the severity of individual PMS symptoms. Furthermore, most studies on homeopathic treatment in PMS are short in duration and have an inadequate sample size. Indeed, only 19 patients completed the RCT carried out by Yakir *et al.* (11 treatment *vs.* 8 placebo)[18] while the RCT of Lapaisant included only 36 patients (21 homeopathy *vs.* 15 placebo).[17] More RCTs are required to take these factors into account and to consider the heterogeneity of this syndrome.

Our study has several important limitations. First, like previous studies, the population treated with homeopathy alone was small and comprised only 23 women. Second, the study was observational in design and was based on the daily clinical practices and diagnosis established by practitioners. No formal criteria, as described in the literature,[2−7] were used to diagnose PMS and the inclusion of patients therefore depended on the competence of the physicians to establish a correct diagnosis. For this reason, and the fact that there was no comparator arm, we cannot conclude further on the efficacy of homeopathic treatment for PMS but simply present the patients as a series of cases. Indeed, previous data in the literature show that over 20% of patients submitted to placebo treatment in PMS studies have a major improvement in their symptoms.[17,18,21] Third, the seven centres involved in this study did not recruit a similar number of women [range: 1−6] and a possible centre effect was not taken into account in the analysis of the results. Fourth, we did not use daily rating forms to record symptoms due to the long study period and because the study was observational in design. This is the most

Table 2 Change in intensity of PMS symptoms between inclusion and follow-up

Symptom	*Aggravation** n *(%)*	*Stable*† n *(%)*	*Improvement*‡ n *(%)*	p *Value*
Mastodynia	0	3 (13)	20 (87)	<0.0001
Irritability, aggression, tension	0	5 (21.7)	18 (78.3)	<0.0001
Feeling depressed	1 (4.3)	14 (60.9)	8 (34.8)	0.014
Asthenia	1 (4.3)	9 (39.1)	13 (56.6)	0.0002
Weight gain, abdominal bloating	0	7 (34.5)	16 (65.5)	<0.0001
Feeling of bearing down	1 (4.3)	11 (47.8)	11 (47.8)	0.001
Heaviness of lower limbs	1 (4.3)	14 (60.9)	8 (34.8)	0.034
Back pain	3 (13.0)	14 (60.8)	6 (26.2)	0.34 (NS)
Headaches	0	15 (65.2)	8 (34.8)	0.003
Skin manifestations	0	16 (69.6)	7 (30.4)	0.007

p Value calculated by a GEE model; NS: not significant.
* Aggravation = change in intensity from absent to mild, mild to moderate, moderate to severe.
† Stable = no change.
‡ Improvement = change in intensity from severe to moderate, moderate to mild or mild to absent.

widely accepted tool to measure patient outcome.[4] Assessment of symptom intensity was subjective and was reported after patient self-rating. However, as our objective was simply to describe the symptoms reported by the patients on which the doctor based his/her diagnosis and not to attribute them to the luteal or follicular phase of the MC we considered that patient self-reporting was adequate for the current study since patients would report those symptoms that were most important to them, either in intensity or impact. We also chose not to record the presence of any major psychiatric comorbidities or other conditions with symptoms that are exacerbated by the MC for a similar reason. Finally, each symptom was given the same weighting and no individual symptom was considered to be more important than another.

Conclusion

This observational study confirms the place of homeopathic medicines in the management of women with PMS. The most frequently prescribed homeopathic medicines were *Folliculinum* and *Lachesis mutus*.

In this study of homeopathy in daily practice, PMS symptoms and QoL were improved by homeopathic treatment. Most therapies ultimately originate from practice experience but should be supported by the results of RCTs conducted to investigate the efficacy of individual homeopathic medicines as a treatment for PMS.

Conflict of interest statement

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