

# Investigating effectiveness of homeopathic treatments for premenstrual disorders

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Homeopathic treatment may be beneficial for women suffering from premenstrual disorders but before this approach can be widely used and accepted, more research is needed. The challenge for the research community is to provide convincing evidence for specific homeopathic treatments which achieve reproducible clinical results and are also easy to implement via existing public healthcare systems. Within the context of a brief overview of important past research in the field, we discuss the on-going 'Dutch International PMS Studies' investigating semi-standardised individualised homeopathic treatment for PMS.

## Premenstrual disorders

Worldwide, up to 30% of women in the fertile age have moderate to severe physical discomfort or feel emotionally unbalanced between ovulation and menstruation.<sup>1</sup> Symptoms such as breast tenderness, water retention, changing moods, depression and extreme irritability can last for several days, or even a fortnight. The commonest forms of this condition are premenstrual syndrome (PMS) or – if mood symptoms predominate – premenstrual dysphoric disorder (PMDD). PMS/PMDD can have a huge impact on a woman's quality of life, as well as leading to increased medical costs,<sup>2</sup> decreased work productivity and increased absenteeism.<sup>3</sup>

## Conventional treatment 'gap'

Women seeking conventional treatment are often prescribed selective serotonin re-uptake inhibitor antidepressants (SSRIs) or an oral contraceptive pill (OCP). Although these drugs can reduce symptoms, they have unpleasant side-effects and do not really cure.<sup>4</sup> Women using SSRIs for PMS report nausea, somnolence, fatigue, decreased libido and sweating.<sup>5</sup> In 2011 the FDA issued a warning about the use of OCPs because of the enhanced risk of thromboembolism.<sup>6</sup> Some women are therefore in desperate need of safe and effective additional/alternative treatments. Homeopathy could well fill this 'gap' but research studies to date have varied greatly in terms of study design, method and quality.

## Non-individualised treatment: *Folliculinum*

*Folliculinum* is a popular homeopathic medicine for PMS made from natural or synthetic oestrogen. In an observational study, 88% of 32 women with menstrual or premenstrual symptoms were satisfied with the overall effects of *Folliculinum C9*<sup>7</sup> and a double blind trial involving 36 women found *Folliculinum C9* to be significantly better than placebo for premenstrual breast pain and breast tension ( $p=0.0159$ ).<sup>8</sup>

## Classical individualised treatment

In a French case series, 23 women with PMS were given individualised homeopathic treatment by seven physicians.<sup>9</sup> 87% of the prescriptions were *Folliculinum 15C* or *30C*. The authors reported an overall statistically significant mean decrease in PMS scores ( $p < 0.0001$ ). Two small double blind placebo-controlled trials have also been published with individualised, classical homeopathic treatment. In one study in the USA, only 10 women could be included and no difference was found between placebo and homeopathy.<sup>10</sup> In a South African study, including 27 women, premenstrual symptoms improved significantly in both homeopathy and placebo groups, but no statistical difference was detected between the groups.<sup>11</sup>

## Semi-standardised individualised treatment

A double blind placebo controlled pilot study with semi-standardised individualised treatment was carried out in Israel, involving 5 homeopathic medicines.<sup>12</sup> Potential patients were pre-screened by questionnaire so that only patients with keynote symptoms of one of these 5 medicines

entered the trial (20 women). Relative improvement of PMS scores was significantly better in the homeopathy group than in the placebo group ( $p=0.048$ ). The same team then conducted a similar study with 96 women, using 14 homeopathic medicines. This also produced positive results which, in collaboration with the Israeli researchers, we aim to publish shortly.

### The Dutch International PMS studies

*a. Observational studies in the Netherlands*  
A study has been initiated in the Netherlands to study the semi-standardised individualised approach further.<sup>13</sup> In usual homeopathic care, women with PMS could be treated with one of over 100 homeopathic remedies, with a lot of variability between prescribers. By focusing on a limited number of frequently used remedies for PMS, combined with well-defined prescription criteria, the semi-standardised protocol ensures that the treatment is reproducible. The Dutch group designed a questionnaire with keynote symptoms for 11 medicines and a computer programme that worked as a simplified repertory. These tools helped to choose one of the 11 selected homeopathic medicines to be prescribed at the 1<sup>st</sup> visit, with the possibility to change the prescription at follow-ups.

The potential effectiveness of using the questionnaire and algorithm in daily practice was evaluated through an observational study in 38 women with 3 months follow-up, in the practices of 15 homeopathic doctors.<sup>14</sup> Following a positive result, the same study was expanded to treat 77 women for 9 months; a clinically relevant drop in PMS scores ( $\geq 50\%$ ) was seen in the majority of women who completed the study (publication in progress).

*b. Multinational randomised controlled pragmatic study.*  
In October 2012, we started an international randomised controlled pilot study in the Netherlands, Sweden and Germany. In phase 1 (on-going), we are evaluating the preferences of 95 women for various conventional and complementary therapies, their expectations, main complaint and general health. The women have been randomised to receive either usual care or usual care plus our semi-standardised homeopathic protocol, over 4 months. Treatment costs will be evaluated for both groups, as well as the nature of the usual care for PMS/PMDD in participating countries. Phase 1 is designed to determine the feasibility of a larger pragmatic trial using the same design (phase 2). Results are expected in 2015.

### Conclusion







Clinical evidence for homeopathic treatment of women with pre-menstrual disorders is promising, but not yet convincing. The Dutch International PMS study has the potential to generate much needed, valuable results, telling us about the clinical effectiveness and cost effectiveness of semi-standardised homeopathic treatment of PMS.

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