



## Women with premenstrual syndrome (PMS) benefit from individualised homeopathic treatment

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### Abstract

In 2019, Yakir et al. published the results of a 'gold standard' (placebo-controlled double-blind randomised) clinical trial on the effectiveness of homeopathy for women suffering from premenstrual syndrome. This study, conducted in Israel, confirmed the positive findings of a smaller pilot study by the same research team: both studies showed beneficial effects of individualised homeopathic treatment in terms of symptom relief, a reduction in days taken as sick leave and decreased use of conventional medication.

### Introduction

Premenstrual syndrome (PMS) affects many women, causing symptoms such as abdominal pain, insomnia, anxiety and irritability before the menstrual period, and requires treatment in up to 20% of women in their reproductive years.<sup>1</sup> Although PMS is widely recognised, and highly prevalent, its cause remains unknown. Several drug treatments are available to reduce PMS symptoms, such as oral contraceptive pills and selective serotonin uptake inhibitors (e.g. fluoxetine/Prozac). However, due to unfavourable side effects, this does not always lead to a satisfactory solution<sup>2</sup>. Instead, some women prefer natural approaches in addition to, or as a replacement for, conventional medicine<sup>3</sup>.

In 2001, a pilot randomised placebo-controlled trial involving 23 Israeli women suggested that homeopathy was effective for treating PMS i.e. women treated with individually prescribed homeopathic medicines had significantly greater symptom improvement, and use fewer conventional drugs, than women treated with placebo. Encouraged by these favourable results, and the potential to identify a natural approach to treating PMS, the researchers repeated the study in a larger sample of women.

The aim of this replication study, described below, was to identify whether individualised homeopathic treatment would be found to be effective for PMS again when repeating the trial with a larger group of patients.

### Patients and methods

Recruitment of patients took place from 1996 to 1999: Women (aged 20 to 50 years) with premenstrual symptoms consulting the gynaecological outpatient clinic of Hadassah University Hospital in Jerusalem, Israel, were enrolled in a 2-month screening phase during which they recorded their premenstrual symptoms daily, using the Menstrual Distress Questionnaire (MDQ) to generate a 'premenstrual score'. Patients were eligible for the study if they received a PMS diagnosis based on their premenstrual score, and their symptoms had a major impact on their daily lives. Included patients completed the homeopathic questionnaire on symptom clusters (see 'Symptom Cluster Approach' below), after which they were interviewed to confirm that the information provided about their symptoms via this homeopathic questionnaire was correct.

### Symptom Cluster Approach

Clinical drug trials usually involve giving the same medication to all participants, making it easy for studies to be replicated to confirm their results. However, in the case of individualised homeopathic treatment, it is essential that the choice of homeopathic prescription is tailored to the specific symptoms being experienced by each patient. Although patients value this personalised approach to treatment, this individualised matching process creates challenges for trial replication.

To overcome this obstacle, a novel treatment protocol – 'symptom cluster approach' – was used. This method, previously tested by the same research team in an earlier pilot study<sup>4</sup> involved women completing a questionnaire to determine whether their symptoms matched one of 14 pre-selected homeopathic medicines. If so, they were entered into the study and prescribed the appropriate medicine. This enabled the essential element of individualisation to be retained, whilst ensuring that the trial can be easily replicated.

105 women were found to be eligible to be treated with one of the 14 homeopathic medicines. After being randomly assigned to the treatment or placebo group, all women received either a single dose of a homeopathic medicine (in 200c potency) or placebo, to be taken once on day 7 of their next menstruation. Symptoms were then monitored by completion of the MDQ for three consecutive months.

### Results

Results were analysed for 96 women: 43 in the homeopathy group and 53 in the placebo group. Comparing the two months prior to treatment, with the three months during treatment:

- There was **greater improvement in premenstrual symptoms in the homeopathy group** compared to the placebo group (p=0.043)
- Women in the homeopathic group **used significantly fewer conventional drugs** during the treatment phase than the placebo group (p=0.043)
- There was a **greater reduction in sick days** reported by women during the treatment phase in the homeopathy group than in the placebo group (p=0.028).

At the onset of the study, the symptoms of women in the two groups, as measured by their mean premenstrual scores, were similar. During the study, both groups improved, but the

reduction in mean premenstrual score was significantly greater in the homeopathy group (0.443 [ $\pm$ 0.32] to 0.287 [ $\pm$ 0.20]), compared to the placebo group (0.426 [ $\pm$ 0.34] to 0.340 [ $\pm$  0.39];  $p = 0.043$ ).

33 women used additional conventional medication during the premenstrual period: 12 in the homeopathy group and 21 in the placebo group. Before treatment, conventional medication use was similar between groups, after treatment conventional medication use was significantly less in the homeopathy group during the 12 premenstrual days (homeopathy group -75% vs placebo -36%) and during the rest of the month (homeopathy group -54% vs placebo -20%).

The percentage of women reporting sick days during the 12 premenstrual days decreased in the homeopathy group (from 35.7% to 21.4%) but hardly changed in the placebo group (32.7% vs 34.6%). The mean reported sick days during the whole month decreased by 74% in the homeopathy group, compared to a reduction of only 7.9% in placebo group ( $p = 0.03$ ).

Furthermore, no serious adverse events were reported during the study.

### Implications for further research

The so-called 'symptom cluster approach' tackles one of the major challenges in clinical research in homeopathy: finding a prescribing method which can be easily reproduced in future trials yet also correctly tailors prescriptions to the symptoms of individual patients. This study demonstrates that effective and replicable homeopathic treatment can be successfully achieved using this fixed protocol. However, as only patients whose symptoms match one of the 14 pre-selected homeopathic medicines can enter the study, this trial design increases the challenge of recruitment.

In this study, only one single dose of the homeopathic medicine was given during the entire duration of the trial. Arguably, it would be more in-line with modern prescribing techniques to repeat the medicine, at least once monthly, for as long as symptoms continue to be present. In future studies the treatment period of 3 months could also be extended to learn more about the potential longer-term benefits of treatment.

### Conclusion

This study confirms the findings of the preceding pilot study, showing that individualised homeopathic treatment is superior to placebo for the treatment of PMS. Women receiving homeopathic treatment had fewer sick days and used less conventional medication, not only during the 12 premenstrual days, but also during the month as a whole, suggesting an additional improvement in general health. Considering the high number of women who suffer from PMS, the findings of this study suggest that, as well as bringing direct clinical benefits to the women involved, homeopathic treatment could also have wider associated economic and sociological benefits.

### Note

*After completion of the larger study in 2002 a first manuscript was drafted but not published in the international peer-reviewed literature. From 2015-2017 a Dutch group prepared an update on the first manuscript in collaboration with the main Israeli researcher (M.Y) which has led to the publication:*

Yakir M, Klein-Laansma CT, Kreitler S, Brzezinski A, Oberbaum M, Vithoulkas G, Bentwich Z. A placebo-controlled double-blind randomized trial with individualized homeopathic treatment using a symptom cluster approach in women with premenstrual syndrome. *Homeopathy* 2019;108:256-269.

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