Trial 2015: Alternative medicine (Herbal)

Effect of Melissa officinalis Capsule on the Intensity of Premenstrual Syndrome Symptoms in High School Girl Students

Link: https://pubmed.ncbi.nlm.nih.gov/26339667/

Year published: 2015

Trial information: Randomised trial.

Objective: The current study aimed to assess the effect of M. officinalis capsule on the intensity of PMS in high-school girls.

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo group.

Participant information: 100 high school girls in Iran.

Treatment length: 3 cycles.

Drug and dosage: 1200 mg of M. officinalis essence daily from the first to the last day of their menstrual cycle (50); or placebo (50).

Measuring scales: The premenstrual symptoms screening tool was used to assess the intensity of PMS symptoms in the two groups before, and one, two, and three months after the intervention. The data were analyzed using paired t-test and repeated measures analysis of variance.

Efficacy outcomes: The results of repeated measures test revealed a significant reduction (P < 0.001) in PMS symptoms. Overall, the mean score of PMS intensity in the intervention group was 42.56 + 15.73 before the intervention and changed to 32.72 ± 13.24, 30.02 ± 12.08, and 13.90 ± 10.22 at the three consecutive months after the intervention, respectively (P = 0.001).

Conclusion : M. officinalis capsules were effective in reduction of the PMS symptoms.

Considerations for future: Application of this medication requires further investigations.

Trial 2012: Alternative medicine (Herbal)

Effect of Vitex agnus castus on women who had PMS, in comparison with placebo

Link: https://pubmed.ncbi.nlm.nih.gov/22359078/

Year published: 2012

Pubmed classification: Randomised Controlled Trial

Objective: The therapeutic effect of Vitex agnus castus on women who had PMS, in comparison with placebo, were investigated.

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo group.

Participant information: 134 women were screened and 128 women confirmed to have PMS completed the study. The mean age was 30.77 (SD=4.37) years in the active group and 30.89 (SD=4.02) years in the placebo group.

Treatment length: 6 cycles.

Drug and dosage: 40 drops of Vitex agnus extract, administered 6 days before menses (62); or placebo (66).

Measuring scales: All patients answered a self-assessment questionnaire about their headache, anger, irritability, depression, breast fullness and bloating and tympani during the premenstrual period before the study and after 6 menstrua cycles. Each item rated using a visual analogue scale (VAS).

Efficacy outcomes: Rank of variables had significant differences in active and placebo groups, before and after the study (P<0.0001); it was noticed that there was a significant difference on Vitex agnus use in comparison with placebo (P<0.0001).

Conclusion: Vitex agnus can be considered as an effective and well tolerated treatment for the relief of symptoms of mild and moderate PMS.

Trial 2010 Alternative medicine (Herbal)

The efficacy of Hypericum perforatum (St John's wort) for the treatment of premenstrual syndrome: a randomized, double-blind, placebo-controlled trial

Link: https://pubmed.ncbi.nlm.nih.gov/20155996/

Year published: 2010

Pubmed classification: Clinical trial.

Objective: To investigate the effectiveness of Hypericum perforatum on symptoms of PMS.

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo controlled - crossover.

Participant information: 36 women aged 18-45 years with regular menstrual cycles (25-35 days), who were prospectively diagnosed with mild PMS.

Treatment length: 2 cycles active drug or placebo; 1 non-treatment cycle; 2 cycles active drug or placebo (+3 screening cycles; +2 cycles placebo run-in phase).

Drug and dosage: Hypericum perforatum tablets 900 mg/day (standardized to 0.18% hypericin; 3.38% hyperforin); or placebo.

Measuring scales: Symptoms were rated daily throughout the trial using the Daily Symptom Report. Secondary outcome measures were the State Anxiety Inventory, Beck Depression Inventory, Aggression Questionnaire and Barratt Impulsiveness Scale.

Plasma hormone (follicle-stimulating hormone [FSH], luteinizing hormone [LH], estradiol, progesterone, prolactin and testosterone) and cytokine (interleukin [IL]-1beta, IL-6, IL-8, interferon [IFN]-gamma and tumour necrosis factor [TNF]-alpha) levels were measured in the follicular and luteal phases during Hypericum perforatum and placebo treatment.

Efficacy outcomes: Hypericum perforatum was statistically superior to placebo in improving physical and behavioural symptoms of PMS (p < 0.05). There were no significant effects of Hypericum perforatum compared with placebo treatment for mood- and pain-related PMS symptoms (p > 0.05).

Plasma hormone (FSH, LH, estradiol, progesterone, prolactin and testosterone) and cytokine (IL-1beta, IL-6, IL-8, IFNgamma and TNFalpha) levels, and weekly reports of anxiety, depression, aggression and impulsivity, also did not differ significantly during the Hypericum perforatum and placebo cycles (p > 0.05).

Conclusion: Daily treatment with Hypericum perforatum was more effective than placebo treatment for the most common physical and behavioural symptoms associated with PMS. As proinflammatory cytokine levels did not differ significantly between Hypericum perforatum and placebo treatment, these beneficial effects are unlikely to be produced through this mechanism of action alone.

Considerations for future: Further work is needed to determine whether pain- and mood-related PMS symptoms benefit from longer treatment duration.

Trial 2010 Alternative medicine (Herbal)

Treatment of moderate to severe premenstrual syndrome with Vitex agnus castus (BNO 1095) in Chinese women

Link: https://pubmed.ncbi.nlm.nih.gov/20334585/

Year published: 2010

Pubmed classification: Randomised Controlled Trial.

Objective: To assess the efficacy of the extract of Vitex agnus castus (VAC, BNO 1095) in the treatment of Chinese women suffering from moderate to severe premenstrual syndrome (PMS).

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo group.

Participant information: 67 Chinese patients with moderate to severe PMS.

Treatment length: 3 cycles.

Drug and dosage: VAC, BNO 1095 - 1 tablet once a day; or placebo.

Measuring scales: Symptoms were documented with a daily rating scale with four symptom factors (negative affect, water retention, food cravings and pain).

Efficacy outcomes: The premenstrual syndrome diary (PMSD) sum score decreased from 29.38 + 7.63 score points at baseline to 4.28 + 5.76 at the 3rd cycle in the treatment group, while it decreased from 28.76 + 7.63 to 11.79 + 7.11.78 in the placebo group. All the four symptom factor scores were significantly reduced by the 3rd treatment cycle.

There was significant difference in PMSD sum score, score of negative affect and water retention between the two groups at cycle 3 (P < 0.05). PMSD sum scores decrease of 60% was defined as efficacy, and the efficacy rate in the treatment group was significantly higher than the placebo group at the 3rd treatment cycle.

Conclusion: Vitex agnus castus extract BNO 1095 shows effectiveness in treating moderate to severe PMS in Chinese women, especially in symptoms of negative affect and water retention.

Trial 2009: Alternative medicine (Herbal)

Treatment for premenstrual syndrome with Vitex agnus castus: A prospective, randomized, multicenter placebo controlled study in China

Link: https://pubmed.ncbi.nlm.nih.gov/19269753/

Year published: 2009

Pubmed classification: Randomised Controlled Trial.

Objective: To investigate the efficacy and safety of VAC BNO 1095 extract in Chinese women suffering from moderate to severe premenstrual syndrome (PMS).

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo group.

Participant information: 217 women were eligible to enter the treatment phase, with moderate to severe PMS. 208 provided the efficacy data, and 202 completed the treatment phase.

Treatment length

3 cycles (+3 cycles screening and preparation).

Drug and dosage: VAC BNO 1095 extract corresponding to 40mg herbal drug (101); or placebo (101).

Measuring scales: Efficacy was assessed using the Chinese version PMS-diary (PMSD) and PMTS.

Efficacy outcomes: The mean total PMSD score decreased from 29.23 at baseline (0 cycle) to 6.41 at the termination (3rd cycle) for the treatment group and from 28.14 at baseline (0 cycle) to 12.64 at the termination (3rd cycle) for the placebo group. The total PMSD score of the 3rd cycle was significantly lower than the baseline in both groups (p<0.0001). The difference in the mean scores from the baseline to the 3rd cycle in the treatment group (22.71+/-10.33) was significantly lower than the difference in the placebo group (15.50+/-12.94, p<0.0001).

Results of PMTS were similar; the total scores for PMTS were significantly lower between the two groups (p<0.01) and within each group (p<0.01). The score was decreased from 26.17+/-4.79 to 9.92+/-9.01 for the treatment group, and from 27.10+/-4.76 to 14.59+/-10.69 for the placebo group. A placebo effect of 50% was found in the present study.

Side-effects assessment: No serious adverse event (SAE) occurred in both groups.

Conclusion: Vitex agnus castus (VAC BNO 1095 corresponding to 40mg herbal drug) is a safe, well tolerated and effective drug of the treatment for Chinese women with moderate to severe PMS.

Trial 2009 Alternative medicine (Acupuncture)

The effect of hand acupuncture therapy and hand moxibustion therapy on premenstrual syndrome among Korean women

Link: https://pubmed.ncbi.nlm.nih.gov/18829443/

Year published: 2009

Pubmed classification: Controlled Clinical Trial.

Further trial information: Quasi-experimental pilot study.

Objective: This study examined the effects of Korean hand acupuncture therapy (HAT) and hand moxibustion therapy (HMT) on symptom severity in Korean women with PMS.

Blind/double blind? Unknown.

Randomised? Unknown.

Placebo? No.

Treatment length: 10 sessions.

Drug and dosage: Korean hand acupuncture therapy (HAT) or hand moxibustion therapy (HMT).

Measuring scales: Outcome measures included menstrual symptom severity as measured with the Menstrual Symptom Severity List and skin temperature change measured with Digital Infrared Thermographic Imaging.

Methodology further information: Based on the khi, yin, yang, and the five elements theory, the study used a nonequivalent control group pretest-posttest design.

Efficacy outcomes: Both experimental groups had significantly reduced overall PMS symptom severity scores following therapy as compared to women in the control group. The HMT but not the HAT group showed improved flow of khi and balanced skin temperature in symmetric body areas.

Conclusion: HAT and HMT may be effective strategies for women to reduce PMS symptoms.

Trial 2009 Alternative medicine (Herbal)

A randomized, placebo-controlled trial of Ginkgo biloba L. in treatment of premenstrual syndrome

Link: https://pubmed.ncbi.nlm.nih.gov/19678774/

Year published: 2009

Pubmed classification: Randomised Controlled Trial.

Objective: We aimed to determine the effect of Ginkgo biloba L. on the symptoms of PMS.

Blind/double blind? Single blind.

Randomised? Yes.

Placebo? Placebo group.

Participant information: 90 university students in Tehran with a PMS diagnosis verified through daily symptom rating forms; 85 completed the study. The active and placebo groups were similar in terms of demographic characteristics and baseline overall severity of symptoms.

Treatment length: 1 cycle (+2 cycles diagnosis).

Drug and dosage: G. biloba L. tablets (containing 40 mg leaf extracts); or placebo three times a day, from the 16th day of the menstrual cycle to the 5th day of the next cycle.

Efficacy outcomes: After the intervention, there was a significant decrease in the overall severity of symptoms and physical and psychologic symptoms in both Ginkgo (23.68%) and placebo (8.74%) groups (p < 0.001). However, the mean decrease in the severity of symptoms was significantly more in the Ginkgo group compared to the placebo group (p < 0.001).

Conclusion: G. biloba L. can reduce the severity of PMS symptoms.

Considerations for future: Further research on active ingredients, and the efficacy and safety of various doses and treatment durations, of Ginkgo are required.

Trial 2008 Alternative medicine (Herbal)

Crocus sativus L. (saffron) in the treatment of premenstrual syndrome: a double-blind, randomised and placebo-controlled trial

Link: https://pubmed.ncbi.nlm.nih.gov/18271889/

Year published: 2008

Pubmed classification: Randomised Controlled Trial

Objective:-To investigate whether saffron (stigma of Crocus sativus L.) could relieve symptoms of premenstrual syndrome (PMS).

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo group.

Participant information: Women 20-45 years with regular menstrual cycles, and experience of PMS symptoms for at least 6 months.

Treatment length: 2 treatment cycles.

Drug and dosage: Saffron capsule 30 mg/day (15 mg twice a day; morning and evening); or placebo capsule (twice a day).

Measuring scales: The primary outcome measure was the Daily Symptom Report, and the secondary outcome measure was the Hamilton Depression Rating Scale.

Efficacy outcomes: In this trial, saffron was found to be effective in relieving symptoms of PMS. A significant difference was observed in efficacy of saffron in cycles 3 and 4 in the Total Premenstrual Daily Symptoms and the Hamilton Depression Rating Scale.

Conclusion: The results of this study indicate the efficacy of C. sativus L. in the treatment of PMS.

Considerations for future: A tolerable adverse effects profile of saffron may well confirm the application of saffron as an alternative treatment for PMS. These results deserved further investigations.

Trial 2005 Alternative medicine (Herbal)

Effect of consumption of soy isoflavones on behavioural, somatic and affective symptoms in women with premenstrual syndrome

Link: https://pubmed.ncbi.nlm.nih.gov/15975174/

Year published: 2005

Pubmed classification: Clinical trial.

Further trial information: Crossover intervention study.

Objective: The effect of isolated soya protein (ISP) containing soy isoflavones (IF) on premenstrual symptom severity was studied.

Blind/double blind? Double-blind.

Randomised? Unknown.

Placebo? Placebo-controlled - crossover.

Participant information: 23 women with prospectively confirmed PMS, aged 18-35 years and BMI 19-30 kg/m.

Treatment length: 7 cycles.

Drug and dosage: Isolated soya protein (ISP) containing 68 mg/d (aglycone equivalents) soy isoflavones (IF); or milk protein placebo.

Measuring scales: ISP containing IF (genistein, daidzein, equol) were measured in 24 h urine samples.

Efficacy outcomes: After two cycles of ISP containing IF intervention, total symptoms (F(2,36) 8.20, P=0.000) and physical symptoms (F(2,36) 8.18, P=0.000) were significantly reduced compared with baseline after both active and placebo treatments, although differences between active and placebo treatment were non-significant.

Specific premenstrual symptoms, headache (F(2,32) 4.10, P=0.026) and breast tenderness (F(2,32) 4.59, P=0.018), were reduced from baseline after soy IF, but not milk protein placebo. Cramps (F(2,32) 4.15, P=0.025) and swelling (F(2,32) 4.64, P=0.017) were significantly lower after active treatment compared with placebo. Concentrations of genistein and daidzein were increased following soy IF consumption, but equol production did not enhance symptom reduction.

Conclusion: The present study showed that ISP containing IF may have potential to reduce specific premenstrual symptoms via non-classical actions.

Trial 2004: Alternative medicine (Herbal)

Flavonoid supplement improves leg health and reduces fluid retention in pre-menopausal women in a double-blind, placebo-controlled study

Link: https://pubmed.ncbi.nlm.nih.gov/14971717/

Year published: 2004

Pubmed classification: Clinical trial.

Further trial information: Pilot study.

Blind/double blind? Double-blind.

Randomised? Unknown.

Placebo? Placebo group.

Participant information: 30 subjects completed the study.

Treatment length: 4 cycles.

Drug and dosage: Daily flavonoid extract - Colladeen, 320 mg oligomeric procyanidins (18); or placebo (12).

Measuring scales: Fluid retention measured at baseline and throughout menstrual cycles using validated questionnaires; and leg girth measured at baseline and end of study.

Efficacy outcomes: Although no significant changes in leg girth measurements were noted, there was a significant improvement in subjective "leg health" scores after flavonoid treatment compared to placebo (p = 0.013). Furthermore, this was accompanied by an improvement in reported premenstrual fluid retention nearing significance (p = 0.066).

Conclusion: We conclude that flavonoids supplements may provide a new therapeutic direction to counter premenstrual fluid retention and improve leg health.

Considerations for future: A larger study is now warranted.

Trial 2004: Alternative medicine (Herbal)

The significance of "nonsignificance" in randomized controlled studies: a discussion inspired by a double-blinded study on (Hypericum perforatum L.) for premenstrual symptoms

Link: https://pubmed.ncbi.nlm.nih.gov/15673985/

Year published: 2004

Pubmed classification: Clinical trial.

Further trial information: Postal trial.

Objective: This study aimed to investigate the efficacy of St. John's wort extract (SJW) as a treatment for premenstrual symptoms.

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo: Placebo group.

Participant information: 169 normally menstruating women who experienced recurrent premenstrual symptoms were recruited onto the UK study. 125 completed the protocol and were included in the analysis.

Treatment length: 2 treatment cycles (+1 baseline cycle).

Drug and dosage: 600 mg of SJW (standardized to contain 1800 microg of hypericin); or placebo (containing lactose and cellulose).

Measuring scales: A menstrual diary was used to assess changes in premenstrual symptoms. The anxiety-related subgroup of symptoms of this instrument was used as the primary outcome measure.

Efficacy outcomes

After averaging the effects of treatment over both treatment cycles, it was found that there was a trend for SJW to be superior to placebo. However, this finding was not statistically significant.

Conclusion: The possibility that this nonsignificant finding resulted from insufficient statistical power in the study, rather than a lack of efficacy of SJW, is discussed.

Considerations for future: Following this discussion the recommendation is made that, in future, similar studies should be powered to detect a minimum clinically relevant difference between treatments.

Trial 2002 Alternative medicine (Acupuncture) Using acupuncture to treat premenstrual syndrome

Link: https://pubmed.ncbi.nlm.nih.gov/12410369/

Year published: 2002

Pubmed classification: Clinical trial.

Blind/double blind? Unknown.

Randomised? Unknown.

Placebo? Placebo group.

Participant information: More than 60% of the women in both groups suffered from premenstrual syndrome (PMS) symptoms, such as anxiety, mastalgia, insomnia, nausea and gastrointestinal disorders, whereas a smaller number of women suffered from phobic disorders, premenstrual headaches and migraines.

There were 3 women from the active group and 7 women from the placebo group who continued the medication treatment with progestins, whereas 1 woman from the active group and 9 women from the placebo group continued to take Fluoxetine.

Treatment length: Unknown.

Efficacy outcomes: In the active group, 9 women stopped having PMS symptoms after two AP treatments; 8 women stopped having them after three treatments; and 1 woman stopped having them after four treatments. In 4 women from the active group and 16 women from the placebo group, PMS symptoms appeared during the following period (cycle) or continued even after four treatments, so the medication was continued.

There was a statistical and relevant reduction in PMS symptoms with the AP treatments in the active group (P<0.001), whereas their reduction was irrelevant in the placebo AP group (P>0.05). The success rate of AP in treating PMS symptoms was 77.8%, whereas it was 5.9%. in the placebo group.

The positive influence of AP in treating PMS symptoms can be ascribed to its effects on the serotoninergic and opioidergic neurotransmission that modulates various psychosomatic functions.

Side-effects assessment: In the active group, one woman had a smaller subcutaneous hematoma after the AP acupoint Ren 6.

Conclusion: The initial positive results of PMS symptoms with a holistic approach are encouraging and AP should be suggested to the patients as a method of treatment.

Trial 2002: Alternative medicine (Herbal)

Randomized, controlled trial of phytoestrogen in the prophylactic treatment of menstrual migraine

Link: https://pubmed.ncbi.nlm.nih.gov/12224599/

Year published: 2002

Pubmed classification: Clinical trial.

Further trial information: Randomised, controlled trial.

Objective: This study was undertaken to assess the efficacy of a phytoestrogen combination in the prophylactic treatment of menstrual migraine.

Blind/double blind? Unknown.

Randomised? Yes.

Placebo? Placebo group.

Participant information: 49 patients.

Treatment length: 24 weeks.

Drug and dosage: Daily combination of 60 mg soy isoflavones, 100 mg dong quai, and 50 mg black cohosh, with each component standardized to its primary alkaloid; or placebo.

Efficacy outcomes: Average frequency of menstrually associated migraine attacks during weeks 9-24 was reduced to 10.3 + - 2.4 (mean +/- s.e.m.) in placebo treated patients; and to 4.7 + - 1.8 (P < 0.01) in patients treated with the phytoestrogen preparation.

Trial 2001 Alternative medicine (Herbal)

Treatment for the premenstrual syndrome with agnus castus fruit extract: prospective, randomised, placebo controlled study

Link: https://pubmed.ncbi.nlm.nih.gov/11159568/

Year published: 2001:

Pubmed classification Clinical trial.

Objective: To compare the efficacy and tolerability of agnus castus fruit with placebo for women with premenstrual syndrome.

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo group.

Participant information: 178 women were screened and 170 were evaluated. Mean age was 36 years; mean cycle length was 28 days; and mean duration of menses was 4.5 days.

Treatment length: 3 cycles.

Drug and dosage: Vitex agnus castus L extract Ze 440, 1 tablet daily (86); or placebo (84).

Measuring scales: Main efficacy variable: Change from baseline to end point (end of third cycle) in women's self-assessment of irritability, mood alteration, anger, headache, breast fullness, and other menstrual symptoms including bloating.

Secondary efficacy variables: Changes in clinical global impression (severity of condition, global improvement, and risk or benefit); and Responder rate (50% reduction in symptoms).

Efficacy outcomes: Improvement in the main variable was greater in the active group compared with the placebo group (P<0.001). Analysis of the secondary variables showed significant (P<0.001) superiority of active treatment in each of the three global impression items. Responder rates were 52% and 24% for active and placebo, respectively.

Side-effects assessment: 7 women reported mild adverse events (4 active; 3 placebo), none of which caused discontinuation of treatment.

Conclusion: Dry extract of agnus castus fruit is an effective and well tolerated treatment for the relief of symptoms of the premenstrual syndrome.

Trial 2001: Alternative medicine (Herbal)

Treatment for the premenstrual syndrome with agnus castus fruit extract: prospective, randomised, placebo controlled study

Link: https://pubmed.ncbi.nlm.nih.gov/11159568/

Year published: 2001:

Pubmed classification Clinical trial.

Objective: To compare the efficacy and tolerability of agnus castus fruit with placebo for women with premenstrual syndrome.

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo group.

Participant information: 178 women were screened and 170 were evaluated. Mean age was 36 years; mean cycle length was 28 days; and mean duration of menses was 4.5 days.

Treatment length: 3 cycles.

Drug and dosage: Vitex agnus castus L extract Ze 440, 1 tablet daily (86); or placebo (84).

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Secondary efficacy variables: Changes in clinical global impression (severity of condition, global improvement, and risk or benefit); and Responder rate (50% reduction in symptoms).

Efficacy outcomes: Improvement in the main variable was greater in the active group compared with the placebo group (P<0.001). Analysis of the secondary variables showed significant (P<0.001) superiority of active treatment in each of the three global impression items. Responder rates were 52% and 24% for active and placebo, respectively.

Side-effects assessment: 7 women reported mild adverse events (4 active; 3 placebo), none of which caused discontinuation of treatment.

Conclusion: Dry extract of agnus castus fruit is an effective and well tolerated treatment for the relief of symptoms of the premenstrual syndrome.

Trial 1993 Alternative medicine (Herbal)

Value of standardized Ginkgo biloba extract (EGb 761) in the management of congestive symptoms of premenstrual syndrome

Link: https://pubmed.ncbi.nlm.nih.gov/8235261/

Year published: 1993

Pubmed classification: Clinical trial.

Further trial information: Controlled multicentric study.

Objective: The efficacy of standardized Ginkgo biloba extract (EGb 761) in treating congestive symptoms of premenstrual syndrome (PMS) was evaluated.

Blind/double blind? Double-blind.

Randomised? Unknown.

Placebo? Placebo group.

Participant information: The population studied was a group of 165 women aged between 18 to 45, suffering for at least 3 cycles from congestive premenstrual troubles during at least 7 days per cycle. The characteristics of patients and PMS were the same in the treatment and placebo groups. From 165 patients, 143 observations were available.

Treatment length: 2 cycles (+1 cycle diagnostic confirmation).

Drug and dosage: EGb 761 from 16th day of the first cycle till the 5th day of the next cycle; or placebo.

Measuring scales: A double evaluation of the symptoms was realized by the patient using a daily rating scale (auto-evaluation); and by the practitioner during visits at the premenstrual phase, before and after the two cycles of treatment.

Efficacy outcomes: With a good acceptability, EGb 761 was effective against the congestive symptoms of PMS, particularly breast symptoms, with a statistical significance between EGb 761 and placebo. Neuropsychological symptoms were also improved.

Conclusion: EGb 761 is an alternative of interest to therapeutics already used in treating PMS or can be associated without any inconvenience.

Trial 1993: Alternative Medicine (Reflexology)

Randomized controlled study of premenstrual symptoms treated with ear, hand, and foot reflexology

Link: https://pubmed.ncbi.nlm.nih.gov/8233263/

Year published: 1993

Pubmed classification: Clinical trial.

Further trial information: Randomised controlled study.

Objective: To determine whether reflexology therapy--the application of manual pressure to reflex points on the ears, hands, and feet that somatotopically correspond to specific areas of the body--can significantly reduce premenstrual symptoms compared to placebo treatment.

Blind/double blind? Unknown.

Randomised? Yes.

Placebo? Placebo group.

Participant information: 35 women who complained of previous distress with premenstrual syndrome (PMS).

Treatment length: 2 months (+2 month pre-trial monitoring; +2 month post-trial monitoring).

Drug and dosage: Ear, hand and foot reflexology; or placebo reflexology, once a week, for 30 minutes. The reflexology sessions for both groups were provided by a trained reflexology therapist.

Measuring scales: All subjects completed a daily diary, which monitored 38 premenstrual symptoms on a four-point scale. Somatic and psychological indicators of premenstrual distress were recorded each day.

Efficacy outcomes: Analysis of variance for repeated measures demonstrated a significantly greater decrease in premenstrual symptoms for the women given true reflexology treatment than for the women in the placebo group.

Conclusion: These clinical findings support the use of ear, hand, and foot reflexology for the treatment of PMS.

Trial 1990 Alternative medicine (Herbal)

Evening primrose oil and treatment of premenstrual syndrome

Link: https://pubmed.ncbi.nlm.nih.gov/2201888/

Year published: 1990

Pubmed classification: Clinical trial.

Objective: To assess the therapeutic effectiveness of evening primrose oil (Efamol, Vita-Glow) in the relief of 10 symptoms associated with premenstrual syndrome (PMS) as well as menstrual symptoms.

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo-controlled - crossover.

Participant information: 38 women.

Treatment length: 3 cycles active drug or placebo; 3 cycles active drug or placebo.

Drug and dosage: Evening primrose oil (Efamol, Vita-Glow); or placebo.

Efficacy outcomes: Although the results showed an improvement in symptoms of PMS during the trial, no significant differences in the scoring between the active and placebo groups were found over six cycles.

No "carry-over" effect of active medication was observed; the beneficial effect on all symptoms (psychological, fluid retention, breast) was rapid, the scores decreasing in the first cycle but increasing slightly at the change-over period after the third cycle, irrespective of whether the active or placebo medication was next given.

Conclusion: These findings indicate that the improvement experienced by these women with moderate PMS was solely a placebo effect