Trial 2011: Diet (Fatty acids)

Essential fatty acids for premenstrual syndrome and their effect on prolactin and total cholesterol levels: a randomized, double blind, placebo-controlled study

Link: https://pubmed.ncbi.nlm.nih.gov/21241460/

Year published: 2011

Pubmed classification: Randomised Controlled Trial.

Objective: To evaluate the effectiveness and safety of polyunsaturated fatty acids for the treatment of the premenstrual syndrome (PMS) using a graded symptom scale; and to assess the effect of this treatment on basal plasma levels of prolactin and total cholesterol.

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo group.

Participant information: 120 women with PMS. There were no differences in age, marital status, schooling or ethnicity between the active and placebo groups.

Treatment length: 6 months.

Drug and dosage: 1g, 2g or placebo.

Measuring scales: Prospective Record of the Impact and Severity of Menstruation (PRISM) calendar. Total cholesterol and prolactin levels were measured. Analysis of variance (ANOVA), Pearson's chi-square test, Wilcoxon's nonparametric signed-rank test for paired samples and the Mann-Whitney nonparametric test for independent samples were used in the statistical analysis.

Efficacy outcomes: In the group treated with 1 gram of the medication, a significant reduction was found when the median PRISM score recorded in the luteal phase at baseline (99) was compared with the median score recorded in the 3rd month (58); and in the 6th month of evaluation (35).

In the 2-gram group, these differences were even more significant (baseline score: 98; 3rd month: 48; 6th month: 28). In the placebo group, there was a significant reduction at the 3rd but not at the 6th month (baseline: 96.5; 3rd month: 63.5; 6th month: 62).

The difference between the phases of the menstrual cycle was greater in the 2-gram group compared to the group treated with 1 gram of the medication. There were no statistically significant differences in prolactin or total cholesterol levels between baseline values and those recorded after six months of treatment.

Conclusion: The difference between the groups using the medication and the placebo group with respect to the improvement in symptomatology appears to indicate the effectiveness of the drug. Improvement in symptoms was higher when the 2-gram dose was used. This medication was not associated with any changes in prolactin or total cholesterol levels in these women.

Trial 1993: Diet (Fatty acids)
Essential fatty acids in the treatment of premenstrual syndrome

Link: https://pubmed.ncbi.nlm.nih.gov/8416468/

Year published: 1993

Pubmed classification: Clinical trial.

Objective: To determine whether essential fatty acids are effective in the treatment of premenstrual syndrome (PMS).

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo controlled – crossover.

Participant information: 27 women diagnosed with PMS; and 22 symptom-free controls

Treatment length: 4 cycles active drug or placebo; 4 cycles active drug or placebo (+1 cycle diagnostic assessment; +1 cycle placebo treatment pre-trial).
Measuring scales: Assessment of symptoms and diagnosis of PMS were based on daily self-ratings made by the women throughout the study.

Efficacy outcomes: Treatment with essential fatty acids did not reduce premenstrual symptoms or symptom cyclicity. However, time had a significant effect on a number of symptoms, indicating either a placebo effect, or an effect from participation in the study

Side-effects assessment: Women with PMS had a significantly higher frequency of dysmenorrhea and familial PMS than the symptom-free controls.

Conclusion: Treatment with essential fatty acids is ineffective therapy for PMS. The improvement we observed over time can be ascribed to either a placebo effect or participation in the study

Trial 2007: Exercise

Exercise training effects on premenstrual distress and ovarian steroid hormones

Link: https://pubmed.ncbi.nlm.nih.gov/17039366/

Year published: 2007

Pubmed classification: Comparative study.

Further trial information: Cross-sectional study, prospective.

Objective: Preliminary studies suggest that moderate physical activity may reduce both premenstrual distress (PD) and the ovarian steroid hormones, progesterone and estradiol, which have been implicated in PD. We attempted to replicate these findings, while exploring possible relationships between hormone levels and PD.

Participant information: Cross-sectional: 20 moderate exercises and 34 sedentary women.
Prospective: 14 sedentary women.

Intervention length: Cross-sectional: 1 cycle.Prospective: 24-week programme.

Intervention: Cross-sectional: Status quo (moderate exercise/sedentary).
Prospective: 24 week moderate exercise-training programme.

Measuring scales: Cross-sectional: Participants completed PD symptom questionnaires and collected urine samples, daily, throughout a complete menstrual cycle. PD was calculated as the difference in symptom scores reported during the average of the 4 days prior to menses and the average of the 4 days closest to mid-cycle. Urine samples taken from the last quarter of the menstrual cycle were analyzed for urinary estrone glucoronide (E1G) and pregnanediol glucoronide.
Prospective: The same measures were used before and after the programme.

Efficacy outcomes: In the cross-sectional study, exercising women reported lower Pain symptoms, and had lower peak E1G levels than sedentary women. The baseline PD symptoms of loneliness, crying, and skin blemishes were statistically significant, and positively correlated with pregnanediol glucoronide levels in the cross-sectional study.

In the prospective study, exercise reduced the global PD symptom score, including the Water Retention and Pain scales, and reduced pregnanediol glucoronide and peak E1G levels.

Conclusion: Moderate aerobic exercise may lessen both PD symptoms and late luteal phase ovarian hormone levels. An exercise program may benefit women with progesterone-related premenstrual affect disturbance

Trial 1993: Exercise

The effects of aerobic exercise on premenstrual symptoms in middle-aged women: a preliminary study

Link: https://pubmed.ncbi.nlm.nih.gov/8463989/

Year published: 1993

Pubmed classification: Clinical trial.

Further trial information: Preliminary study.

Objective: To assess the effect of aerobic exercise and strength training on premenstrual symptoms.

Randomised? Unknown.

Participant information: 23 healthy premenopausal women.

Intervention length: 3 months.

Intervention: Aerobic exercise; or anaerobic exercise (strength training).

Measuring scales: Premenstrual symptoms were assessed at baseline and following 3 months of exercise participation.

Efficacy outcomes: Women who engaged in aerobic exercise significantly increased their aerobic capacity, while the women who participated in non-aerobic exercise did not. Results showed that while participation in both exercise conditions was associated with general improvement in many premenstrual symptoms, subjects in the aerobic exercise group improved on more symptoms, especially premenstrual depression.

Trial 1987: Exercise
Conditioning exercise decreases premenstrual symptoms: a prospective, controlled 6-month trial

Link: https://pubmed.ncbi.nlm.nih.gov/3549364/

Year published: 1987

Pubmed classification: Clinical trial.

Further trial information: Prospective controlled trial.

Participant information: 7 marathon runners; 6 active non-training women; and 8 sedentary women.

Intervention length: 6 months.

Intervention: Sedentary (ST) women increased running from 0 to 76 +/- 26 km/cycle (mean +/- standard deviation); seven runners (MT) trained for a marathon (42.2 km). Normally active, nontraining (C-NT) women kept their activity constant.

Measuring scales: Each subject completed monthly intensity-graded questionnaires or kept daily symptoms diaries concerning premenstrual symptoms. All monitored basal body temperature, weight, and exercise. Gonadal steroids were measured in ST women.

Efficacy outcomes: For ST subjects, breast ($P = 0.005$), fluid ($P = 0.01$), and personal stress ($P = 0.025$) decreased. MT women experienced decreased fluid ($P = 0.034$) and depression ($P = 0.014$). Anxiety tended to decrease ($P = 0.087$). ST and MT subjects experienced decreases in premenstrual symptoms without documented hormonal, menstrual cycle, or weight changes.

Conclusion: These symptom changes appear to be the earliest evidence of the effects of conditioning exercise on the reproductive system.

Trial 1986: Exercise
Conditioning exercise decreases premenstrual symptoms. A prospective controlled three month trial

Link: https://pubmed.ncbi.nlm.nih.gov/3758033/

Year published: 1986

Trial information: Prospective controlled trial.

Objective: To assess the effect of conditioning exercise on premenstrual syndromes.

Participant information: 8 women with normal ovulatory menstrual cycles; and 6 sedentary control women.

Intervention length: 3 months.

Intervention: Running exercise training programme.

Measuring scales: Participants completed intensity-graded questionnaires concerning molimina. Oral basal temperatures, evaluated by mean temperature analysis, were obtained for all cycles. Exercise distance and time, average exercise heart rate, basal and maximal heart rate and body weights were recorded prospectively and evaluated during the control (0) and 3rd month of the study. Mid-luteal phase progesterone and estrogen levels were sampled during the analyzed cycles for the exercise group.

Efficacy outcomes: Molimina did not change over 3 months in the control group. The exercise group, after increasing distance run to 51.0 +/- 18.1 km/cycle at 3 months, showed decreases in overall molimina (scores on a 9-point scale) 6.5 +/- 1.8 to 3.5 +/- 0.9, p less than 0.01).

Breast symptoms decreased from 8.3 +/- 0.7, p less than 0.005. Fluid symptoms also decreased from 7.3 +/- 1.8 to 5.5 +/- 0.9, p less than 0.025. Menstrual cycle intervals, luteal lengths, body weights and mid-luteal estrogen and progesterone levels were normal and unchanged.

Conclusion: Moderate exercise training without major weight, hormonal or menstrual cycle alteration significantly decreased premenstrual symptoms.

Trial 1995: Diuretics (Spironolactone)

Treatment of premenstrual syndrome by spironolactone: a double-blind, placebo-controlled study

Link: https://pubmed.ncbi.nlm.nih.gov/8533564/

Year published: 1995

Pubmed classification: Clinical trial.

Objective: To re-evaluate whether spironolactone, a steroid receptor antagonist, is effective in improving premenstrual syndrome (PMS).

Blind/double blind? Double-blind.

Randomised? Unknown.

Placebo? Placebo controlled - crossover study.

Participant information: 35 women with PMS.

Treatment length: 6 cycles (+ 2 pre-treatment cycles).

Drug and dosage: 1 tablet of 100mg spironolactone daily from day 14 of the menstrual cycle until the first day of the following menstruation; or placebo. Spironolactone and placebo were applied in either the first or second 3 months.

Measuring scales: Prospective daily self-ratings made by the women using a validated visual analogue scale.

Efficacy outcomes: The treatment with spironolactone was associated with an improvement in PMS symptoms compared to placebo as judged by significant decrease in negative mood symptom scores ($p < 0.001$) and somatic symptom scores ($p < 0.001$).

Of the individual symptoms, Spironolactone significantly improved irritability, depression, feeling of swelling, breast tenderness and food craving in comparison to placebo. A lasting effect of Spironolactone was observed in women started with Spironolactone after cross over to placebo.

Conclusion: Spironolactone appears to be an effective therapy for the negative mood changes and somatic symptoms in PMS.

Trial 1979: Diuretics (Spironolactone)
Treatment of premenstrual syndrome by Spironolactone

Link: https://pubmed.ncbi.nlm.nih.gov/371663/

Year published: 1979

Pubmed classification: Clinical trial.

Blind/double blind? Double-blind.

Randomised? Unknown.

Placebo? Placebo controlled – crossover.

Participant information: 28 women.

Treatment length: 4 cycles.

Drug and dosage: Spironolactone, no dose given.

Measuring scales: Hormonal profiles were measured during the first 2 cycles.

Efficacy outcomes: Plasma aldosterone was elevated in the premenstrual phase of the cycles but there was no significant difference between symptomatic and asymptomatic groups. The rise in serum progesterone was higher in the symptomatic group during the postovulatory phase. The administration of spironolactone reduced weight and relieved psychological symptoms in more than 80 per cent of the symptomatic group.