

## **A randomised placebo controlled clinical trial on the efficacy of chiropractic therapy on premenstrual syndrome.**

Max Walsh (*MSc, BAppSc(Chiro), BSc, GradDipMuscMgt, DipEd*)

Barbara Polus (*PhD, MSc, BAppSc(Chiro)*)

Department of Chiropractic, Osteopathy & Complementary Medicine

RMIT University - Bundoora, Melbourne, Australia

### **BACKGROUND**

Premenstrual syndrome (PMS), also known as Late Luteal Phase Dysphoric Disorder (LLPDD), describes a wide range of presenting signs and symptoms suffered during the premenstrual phase of the menstrual cycle (1). Currently, PMS is regarded as a milder version of Premenstrual Dysphoric Disorder for which research criteria has been included in the DMS-IV (2,3).

It is estimated that 10-20% of women of reproductive age experience severe or disabling symptoms with up to 95% of such women experiencing some form of PMS (4,5). Over 150 symptoms have been identified including psychological problems e.g. irritability, mood changes, anger and depression, physical symptoms like abdominal cramping, breast tenderness, low back pain and headaches, and joint pain, and behavioral changes e.g. food craving, insomnia, and loss of libido (4).

There are many postulated etiologies, and various treatment regimes that are used to manage PMS (6). The major non-chiropractic therapeutic intervention for PMS sufferers involves a wide variety of drugs, as well as psychotherapy, vitamin supplements, diet control, exercises, and lifestyle management. Several authors (7,8) have reviewed the major therapeutic interventions and found them in general to be ineffective when compared to placebo effects, or to have undesirable side effects. Recent research (9,10) has indicated that drugs such as fluoxetine (prozac) and sertraline that affect serotonin activity and reuptake, may be effective in the treatment of PMS and PMDD. Anecdotal evidence of the effectiveness of chiropractic manipulative therapy (CMT) in reducing the symptoms associated with PMS is abundant, but no clinical trials have been performed. Published case studies (11-14) offer some support for the anecdotal evidence.

### **Definition and diagnosis of PMS**

To make a diagnosis of PMS, the signs and symptoms must occur cyclically, particularly in the luteal phase of the menstrual cycle. Also, during the follicular phase there should be at least seven symptom-free days in each cycle.

There are no biological markers for PMS, and the diagnosis by necessity is made on the history and particularly on prospective recording of signs and symptoms on a daily basis. Retrospective evaluations have been found to be very unreliable, while self-diagnosis has been estimated to be incorrect in up to 50 per cent of patients (7).

Other disorders that may contribute to PMS symptoms and need to be ruled out prior to treatment for PMS include thyroid disease, mammary dysplasia, polycystic ovary syndrome, and galactorrhoea (5).

## **OBJECTIVES:**

To evaluate the efficacy of chiropractic therapy on the treatment of symptoms associated with premenstrual syndrome (PMS).

## **METHODS**

The trial design was a randomised, single blind placebo controlled cross-over clinical trial. The subjects were female of reproductive age with diagnosable PMS (according to DMS -III-R criteria) and regular menstrual cycles. They were excluded from the study if they had medically diagnosed psychiatric, gynecological or hormonal disorders, had had chiropractic treatment in the previous six months, were on medications that affected the menstrual cycle or had contraindications to chiropractic manipulation.

A sample of 54 women with diagnosable premenstrual syndrome were initially recruited. All subjects underwent an initial interview and examination. Those that satisfied the DMS -III criteria for PMS and had no contra-indications to chiropractic therapy were admitted to the study. The subjects monitored their major PMS symptoms on a daily basis for two complete cycles prior to any intervention. Forty-five subjects had symptom patterns consistent with PMS and were divided randomly into two groups. Group 1 (n=28) initially received chiropractic treatment for three cycles, followed by the placebo consisting of a sham adjustment for a further three cycles after a one cycle wash-out. Group 2 (n=17) received the placebo first then the treatment. Treatment consisted of standard manual or drop-piece adjustments as indicated and soft tissue therapy. The sham treatment utilised an activator adjusting instrument wound fully down. Subjects monitored their PMS symptoms on a daily basis for the full course of the trial. A global score was calculated for each subject as a measure of the symptom severity for the premenstrual week for all phases of the trial. Statistical analysis: The total symptom scores for the premenstrual week for the base line period were compared to the treatment phase, and the treatment phase scores compared to the placebo phase. In each case, paired t-tests and Wilcoxon Signed Rank tests were calculated with the statistical significance set at  $p < 0.05$ .

## **RESULTS**

A total of 25 subjects completed all phases of the study. Preliminary analysis was done using paired t-tests and Wilcoxon tests to compare base vs treatment and treatment vs. placebo global scores for the total sample.

There was a significant decrease in scores following treatment compared to base line scores ( $p=0.00001$ ), and a statistically significant decrease in scores for the treatment phase compared to the placebo ( $p=0.006$ ).

For Group 1 (n=16), there was a significant decrease in scores following treatment compared to base line scores ( $p=0.0001$ ), and a statistically significant decrease in scores for the treatment phase compared to the placebo ( $p=0.041$ ). For Group 2 (n=9), there was a significant decrease in scores during treatment compared to the base line ( $p=0.01$ ), however, there was no difference at the  $p=0.05$  level between treatment and placebo scores.

## CONCLUSIONS

Within the limitations of the study, the results support the hypothesis that the symptoms associated with PMS can generally be reduced by chiropractic treatment consisting of adjustments and soft tissue therapy. However, the role of a placebo effect needs further elucidation, given that the group receiving the placebo first, while improving over the base line, showed no further improvement when they had actual treatment.

## ACKNOWLEDGEMENT

This study was funded by the Australian Spinal Research Foundation.

## REFERENCES

1. Huerta MR, Malacara JM. Association of physical and emotional symptoms with menstrual cycle and life-style. *J Reprod Med* 1993; 38:448-54.
2. Steiner M. Premenstrual dysphoric disorder: an update. *Gen Hosp Psychiatry* 1996 18(4):244-250.
3. American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 4th ed. Washington DC; AMA, 1994:715-18.
4. Sveinsdottin H and Reame N. Symptom patterns of women with PMS complaints. *J Adv Nurs* 1991; Jun 16(6):689-700.
5. Smith M. Premenstrual syndrome. *MIMS Disease Index 1st Ed.* IMS Publishing NSW 1991/2: 439-441.
6. Walsh MJ. Premenstrual syndrome: A clinical update for the chiropractor. *Chiropr J Aust* 1993; 23:48-53.
7. Chihal HJ. Premenstrual syndrome: an update for the clinician. *Obstet Gyn Clinics of Nth America* 1990; po17(2): 457-479.
8. Steinberg S. the treatment of late luteal phase dysphoric disorder. *Life Sciences* 1991; 49: 767-802.
9. Ozeren S, Corakci A, Yucesoy I, Mercan R, Erhan G. Fluoxetine in the treatment of premenstrual syndrome. *Eur J Obstet Gynecol Reprod Biol* 1997 73(2):167-170.
10. Yonkers KA, Halbreich U, Freeman E, Brown C, Pearlstein T. Sertraline in the treatment of premenstrual dysphoric disorder. *Psychopharmacol Bull* 1996; 32(1): 41-46.
11. Hubbs EC. Vertebral subluxation and premenstrual tension syndrome: a case study. *Res Forum* 1986; 2:100-2.
12. Stude DE. The management of symptoms associated with premenstrual syndrome. *J Manipulative Physiol Ther.* 1991; 14(3):209-15.
13. Smith VC, Rogers SR. Premenstrual and postmenstrual syndrome, its characteristics and chiropractic care. *The American Chiropractor* 1992; Mar: 4-6.
14. Walsh MJ, Chandraraj s, Polus BI. the efficacy of chiropractic therapy on premenstrual syndrome: a case series study. *Chiropr J Aust* 1994; 24 (4):122-126.