

The National Association for Premenstrual Syndrome

(NAPS)

Guidelines on Premenstrual Syndrome



Nick Panay

BSc MRCOG MFSRH

NAPS Guidelines on Guidelines on Premenstrual Syndrome

Nick Panay BSc MRCOG MFSRH

Chairman of the National Association for Premenstrual Syndrome

Director of West London Menopause & PMS Centre

Consultant Gynaecologist

Imperial College Healthcare NHS Trust & Chelsea and Westminster

NHS Foundation Trust

Honorary Senior Lecturer, Imperial College London

INTRODUCTION

These guidelines have been prepared by Mr Nick Panay, Chairman of NAPS for the benefit of both sufferers and health professionals. The guidelines aim to provide clear information at a time when so much controversy exists as to the causality and management of PMS. Guidelines on the definition and management of PMS are essential to encourage the acceptance of the condition by patients, health professionals and regulatory authorities. The text aims to distil the evidence base into easily digestible and understandable prose – as such, extensive references will not be provided but are available from the Green Top Guidelines of the Royal College of Obstetricians and Gynaecologists www.rcog.org.uk for the interested reader. The treatment algorithm provides a summary of interventions which might be instituted at levels of the severity of symptoms. In the Appendix, levels of recommendation are given for the medical interventions according to accepted RCOG evidence levels with also key references and further reading.

DEFINITION

Many women experience mild physical and emotional PMS symptoms which are not particularly troublesome. However, when severe, these symptoms can lead to a breakdown in interpersonal relationships and to an interference with normal activities. A working definition of PMS is “a con-

dition which manifests with distressing physical, behavioural and psychological symptoms not due to organic or underlying psychiatric disease, which regularly recurs during the luteal phase of each menstrual (ovarian) cycle and which disappears or significantly regresses by the end of menstruation.” The severity of symptoms is judged according to the degree of interference with day-to-day activities and relationships. Premenstrual exaggeration or exacerbation of symptoms can also occur, though this is not regarded as the “core” diagnosis. Premenstrual Dysphoric Disorder (PMDD) is the American Psychiatric Association’s definition of severe PMS in the Diagnostic and Statistics manual - Version IV

AETIOLOGY

The precise aetiology of PMS remains unknown but cyclical ovarian activity and the effect of estradiol and progesterone on the neurotransmitters serotonin and gamma-aminobutyric acid (GABA) appear to be key factors. Absence of PMS before puberty, in pregnancy and after the menopause supports the theory that cyclical ovarian activity is important. Rapidly changing estradiol levels, not only premenstrually but also postnatally and perimenopausally lead to this triad of hormone dependent depressive disorders often in the same predisposed individual. Recent work has shown that the risk for PMDD is associated with a genetic variation in ESR1 (Estrogen Receptor [ER] alpha) gene but more work is required to confirm and define this genetic predisposition.

PREVALANCE

The reported prevalence of moderate to severe PMS varies between 3% and 30%, depending on the population studied, and is likely to be under reported, especially by the ethnic minorities. The incidence of severe PMS or PMDD appears to be 5 to 8%. PMS appears less prevalent in women who are on hormonal contraception, of normal weight and perform exercise.

DIAGNOSIS

Crucial to the management of PMS is the need to make the correct diagnosis. This cannot be accurately established by retrospective recall. It needs to be made by the prospective logging of symptoms by the patient, ideally over two cycles. A symptom chart/diary which can be filled in online is available on the NAPS website (www.pms.org.uk). Alternatively, the 'blue moons' diary could be used. The chart/diary should continue to be filled in when treatment has been started to give an objective indication of response to therapy.

Common Symptoms of PMS (over 150 identified)

PSYCHOLOGICAL & BEHAVIOURAL SYMPTOMS

Mood swings, depression

Tiredness, fatigue or lethargy, irritability

Anxiety, feeling out of control

Reduced cognitive ability, aggression, anger

Sleep disorders, , food cravings

PHYSICAL SYMPTOMS

Breast tenderness, skin rashes

Bloating, weight gain, clumsiness

Headaches, backache

TREATMENT

General Principles of Treatment

When managing women with PMS, there are certain principles which should be adhered to. Even though not evidence-based, there is little doubt

that reduction of stress, for instance, is a great help in ameliorating symptoms. Also, dietary measures such as avoidance of carbohydrate binges and limitation of alcohol and caffeine intake is often of benefit. There are data from non-randomised trials that exercise improves PMS symptoms. However, in cases of moderate to severe PMS, it is important that medical therapy is instituted sooner rather than later to avoid unnecessary suffering. Women with marked underlying psychopathology as well as PMS should be referred to a psychiatrist. Symptom charts/diaries should be used to assess the effect of treatment.

Service Delivery

Primary care should be able to deal with most cases of PMS. Awareness of the condition and training in its management are essential. Ideally, women with severe PMS should be treated by a multidisciplinary team which might comprise a hospital or community gynaecologist, psychiatrist or psychologist, dietitian and counsellor. While such services are rarely provided in any NHS setting, referral to a gynaecologist should be reserved for women who have been fully evaluated as having severe PMS and when simpler forms of therapy have been explored.

COMPLEMENTARY THERAPIES (CAMs)

When treating women with PMS, complementary medicines may be of benefit, but clinicians need to consider that data from clinical studies are limited and underpowered. Interactions with conventional medicines should also be considered. It is difficult to assess the true value of most of these therapeutic interventions because they are freely available without prescription or physician recommendation, and with little regulation of efficacy or safety. Most are not licensed or registered for the treatment of PMS. The regulatory authorities are aiming to rectify the situation by insisting that all complementary therapies are registered by 2011 or withdrawn from sale. This section reviews the recent evidence for some of the evidence-based

'alternative' interventions which have been used to treat PMS. Treatments have been selected where reasonable efficacy data exist (randomised controlled data if possible).

Vitamin B6^{OTC} IS

Vitamin B6 is often used to treat premenstrual syndrome without clear evidence of its efficacy. The recommended dietary allowance for Vitamin B6 is around 2.0mg/day and deficiency of Vitamin B6 is rare. Due to the unproven efficacy of Vitamin B6 in treating premenstrual syndrome, a systematic review of published and unpublished randomised placebo controlled trials of effectiveness of Vitamin B6 in the management of premenstrual syndrome has been undertaken. This showed a marginal benefit for using Vitamin B6. There is no rationale for giving daily doses of Vitamin B6 in excess of 100mg, especially following recommendation from the Department of Health and the Medicine Control Agency in 1999 to restricting the dose of Vitamin B6 available generally to 10mg and to limit the dose sold by a pharmacist to less than 50mg.

Recommendation (A): Insufficient evidence of efficacy is available to give a recommendation for using Vitamin B6 in the treatment of premenstrual syndrome.

Magnesium^{OTC}

Preliminary small studies suggest that magnesium may also be helpful in PMS. More data would be desirable.

Recommendation (B): There is some evidence that regular use of magnesium supplements is of benefit in managing premenstrual syndrome.

Calcium / Vitamin D^{OTC}

Studies suggest that blood calcium and Vitamin D levels are lower in women with PMS and that calcium supplementation may reduce symptom severity, but it is unknown whether this may prevent the initial development of PMS. In a recent case control study, after adjustment for risk factors,

women in the highest quintile of total Vitamin D intake (median, 706 IU/d) had a relative risk of 0.59 (95% confidence interval, 0.40-0.86) compared with those in the lowest quintile (median, 112 IU/d) (P = .01 for trend). The intake of skimmed or low-fat milk was also associated with a lower risk (P<.001). A high intake of calcium and Vitamin D may therefore reduce the risk of PMS but large-scale clinical trials addressing this issue are required. At present, the only interventional data are from small trials.

Recommendation (B): Given that calcium and Vitamin D may also reduce the risk of osteoporosis and some cancers, clinicians may consider recommending these nutrients even for women with PMS but more data are required to determine efficacy and to optimise regimens.

Isoflavones e.g. Soy/Red Clover^{OTC}

In a 24-week, double-blind study, 49 women with menstrual migraines received either placebo or a combination supplement containing Soy isoflavones, Dong Quai, and Black Cohosh extracts. The treatment group showed a significantly greater improvement than the placebo group. Recent randomised controlled trial data from the author's unit, in 19 women with severe PMS, demonstrate a benefit with Red Clover isoflavones. There was a statistically significant improvement in symptoms from baseline but not significantly different from placebo – a larger study may have demonstrated such a difference.

Recommendation (B): More data are required before a clear recommendation can be made for isoflavone usage but preliminary data are encouraging.

Agnus Castus^{OTC}

The fruits of *Vitex agnus castes* (The chaste tree) contain a mixture of iridoids and flavonoids. The mechanism of action may be related to modulation of stress induced prolactin secretion via dopamine without directly affecting luteinising or follicle stimulating hormones. A number of small

randomised controlled trials show a benefit versus placebo.

Recommendation (B): Agnus Castus is the best researched CAM for PMS but a lack of standardised quality controlled preparations is a problem.

St John's Wort^{OTC}

Hypericum perforatum is a herbal remedy (St John's Wort) shown to alleviate mild to moderate depression. However, there have been no clinical investigations on its effectiveness in treating premenstrual syndrome apart from one case report and a small prospective, open, uncontrolled, observational pilot study. Symptoms which improved the most were emotional and cognitive, which correlates with evidence showing that Hypericum has positive effects on mood and that it may moderate brain neurotransmitters but caution should be exercised in its usage in view of its multiple interactions.

Recommendation B: Initial data appear encouraging but larger studies are required before St John's Wort can be recommended for use in PMS

Evening Primrose Oil^{OTC IE}

Evening Primrose Oil, a rich source of gamma linoleic acid, is often used as a treatment for severe premenstrual syndrome. However, the evidence for efficacy in this condition is poor. A meta-analysis of the data has also concluded that Evening Primrose Oil is ineffective in the treatment of severe PMS. Only cyclical mastalgia (breast pain) has been shown to respond to this treatment.

Recommendation (A): Evening Primrose Oil should be avoided as a treatment for severe PMS unless the treatment is specifically targeted for cyclical mastalgia.

NAPS is a registered charity set up in 1984 which aims to help all sufferers of PMS by providing information and support so that the condition can be successfully managed. The Association works with health professionals both to promote research and to help ensure that PMS sufferers can access treatments appropriate to their needs.

If you would like to purchase further copies of the NAPS Guidelines price £5.00 please contact NAPS at: www.pms.org.uk

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NAPS
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MEDICAL TREATMENT OF PMS

Most efficacious treatments for PMS are unlicensed for use in women with severe PMS. However, in this situation unlicensed treatments can be justified where a body of evidence and safety exist. The two chief evidence-based medical treatments of moderate to severe PMS are categorised by ovulation suppression and selective serotonin reuptake inhibitors

Ovarian suppression

Although the underlying cause of severe PMS remains unknown, cyclical ovarian activity appears to be an important factor. A logical treatment for severe PMS, therefore, is to suppress ovulation and thus suppress the cyclical endocrine/biochemical changes which cause the distressing symptoms. A number of drugs are capable of performing this function, but they are not without their own side-effects which may influence the efficacy of the treatment or the duration for which they may be given.

The combined oral contraceptive pill*

Although able to suppress ovulation, and used commonly to improve PMS symptoms, the combined pill was initially not shown to be of benefit in randomised prospective trials. This is probably because it was used with a pill-free week and because the daily progestogen in the second generation pills e.g. levonorgestrel, regenerated PMS-type symptoms. The relatively new combined contraceptive pill (Yasmin), containing an anti-mineralocorticoid and anti-androgenic progestogen, drospirenone showed considerable promise in the treatment of severe PMS as it minimised progestogenic side-effects with a mild diuretic and anti-androgenic effect. Both observational and small randomised trial data supported efficacy. However, the development of Yasmin has now been succeeded by Yaz®, a 20 microgram ethinylestradiol / 3 mg drospirenone pill but in a 24/4 rather than the conventional 21/7 regimen. The reduction of the hormone free interval to four days reduces the risk of cycle-related symptoms. Two randomised prospective studies trials have demonstrated efficacy of Yaz® over placebo in the treatment of PMDD. If the “conventional” 21/7 regimen pill is used to treat severe PMS, pill packets should be used back to back (bicycling/tricycling) to avoid the regeneration of cycle-related symptoms during the hormone free interval. There are data supporting the continuous use of the pill with a break only introduced if breakthrough bleeding occurs.

Recommendation A:

When treating women with PMS, newer contraceptive pill types may represent effective treatment for PMS and should be considered as one of the first-line pharmaceutical interventions.

Transdermal estradiol*

Placebo-controlled trials have demonstrated that implanted and transdermal (patch) 17β estradiol combined with cyclical progestogen is effective for the management of physical and psychological symptoms of severe PMS. Implants are less commonly used for PMS since patches have become available due to their long lasting effects. A recently concluded study from the author's unit has shown benefits of 100mcg patches over placebo with benefits lasting up to 14 months. Additional barrier or intrauterine methods of contraception should be used when estradiol (patches and implant) are used in PMS as ovulation suppression cannot be guaranteed. There are insufficient data to confirm long-term endometrial and breast safety because long-term randomised prospective safety studies are lacking. However, logic dictates that the hormonal environment is not significantly different from how it would otherwise be in this premenopausal population and observation has not shown any problems over 20 years of usage.

Recommendation A:

Percutaneous estradiol, either as an implant or as a patch, combined with cyclical progestogen, has been shown to be effective for the management of physical and psychological symptoms of severe PMS.

Progestogen intolerance

Use of continuous estradiol normally necessitates the addition of cyclical progestogen (10 - 12 days) to avoid endometrial build-up in women who have a uterus. The progestogen releasing system (Mirena) can maximise efficacy by minimising PMS-like adverse effects. Even the low systemic levels of levonorgestrel released by the Mirena, can initially produce PMS-type adverse effects in the progestogen intolerant woman. Despite this, it might still be of advantage to use a Mirena or vaginal progesterone (Cyclogest pessaries or Crinone gel 8% – not licensed for this indication) in the progestogen intolerant woman.

Recommendation: A

When treating women with PMS, treatment with the lowest possible dose of progestogen is recommended to minimise adverse effects.

Danazol^{HS}

Cycle suppression may be achieved using Danazol, an androgenic steroid. Studies have demonstrated benefit for several symptoms, but due to masculinizing side-effects, especially at higher, cycle-suppressing doses, it is not commonly used.

Recommendation: A

Effective in PMS but side effects and risks outweigh benefits

Gonadotrophin releasing hormone (GnRH) analogues^{HS}

GnRH analogues have been very successfully employed for many years to suppress ovarian steroid production. Early resort to GnRH therapy for PMS is not recommended due to the potential side-effects and cost. Prolonged use should be retained for women with the most severe symptoms. A recent meta-analysis of GnRH analogues has confirmed their efficacy compared with placebo. Data show that symptoms due to the hypoestrogenic state can be virtually eliminated and bone mineral density can be maintained by the use of HRT. Continuous combined therapy or Tibolone is preferable to sequential combined therapy in order to minimise the risks of symptom re-appearance of PMS-like progestogenic effects.

When treating women with PMS, with GnRHa therapy, treatment should only be continued for 6 months when used alone. Treatment should be combined with HRT to reduce bone density loss. Women on long-term treatment should have annual measurement of bone mineral density (ideally by dual energy X-ray absorptiometry). Treatment should be stopped if bone density declines significantly in scans performed one year apart. General advice about how exercise, diet and smoking affect bone mineral density should be given.

Recommendation A

GnRH analogue therapy results in profound cycle suppression and elimination of premenstrual symptoms. Lack of effectiveness suggests a questionable diagnosis rather than a limitation of therapy.

Progesterone^{IE} and Progestogens^{IE}

A recent meta-analysis of all published studies for progestogen and progesterone treatment of PMS demonstrated no benefit for treatment. The objective of this systematic review was to evaluate the efficacy of progesterone and progestogens in the management of premenstrual syndrome. All the trials of progesterone (by both routes of administration) showed no clinically significant difference between progesterone and placebo. The findings of this study were not entirely surprising. Synthetic progestogens actually have PMS-like side effects! Natural progesterone could actually have some benefits as it can have an anxiolytic effect and act as a mild diuretic. Some women find it very therapeutic, even over long periods of time. However, of the few underpowered studies conducted only one has shown benefit and better data are needed.

Depot medroxyprogesterone acetate (Depo Provera), Etonorgestrel rods (Implanon) and the ovulation suppressing progestogen-only pill (Cerazette) all have ovulation suppressant activity. However, cyclical symptoms can be replaced by continuous low grade symptoms due to the PMS-like side-effects of synthetic progestogens. Data regarding efficacy are therefore either absent or at best contradictory.

Recommendation Ia A:

There are insufficient data to recommend the routine use of progestogens or natural progesterone in the treatment of PMS.

Hysterectomy

Total abdominal hysterectomy and bilateral salpingo-oophorectomy is the ultimate form of ovulation suppression and the only true cure for PMS as this removes the ovarian cycle completely. The procedure is only rarely performed for this indication, as a lesser alternative can usually be found. When treating women with PMS, surgery should not be contemplated without pre-operative use of GnRH analogues as a test of cure and to ensure that HRT is tolerated. Such therapy should be reserved for sufferers of extremely severe PMS in whom other treatment has failed. When appropriately targeted, this intervention can have life altering benefits. It is essential that adequate hormone therapy is given (including consideration of testosterone replacement) to prevent simply replacing one set of symptoms with another. Women who have had a hysterectomy with ovarian conservation will often continue to have cyclical symptoms in the absence of menstruation.

Recommendation C:

When treating women with severe PMS, hysterectomy and bilateral salpingo-oophorectomy has been shown to be of benefit.

Selective serotonin reuptake inhibitors (SSRIs)

There is increasing evidence that serotonin may be important in the causality of PMS. A number of SSRIs have been used to treat severe PMS/PMDD. There are also data suggesting improvement of physical symptoms with SSRIs though this is probably due to the improved perception rather than genuine reduction in symptom severity. A meta-analysis of all available randomised controlled trials involving SSRIs used in premenstrual syndrome confirmed superior efficacy compared with placebo.

The Commission on Human Medicines endorses the view that SSRIs are effective medicines in the treatment of depression and anxiety conditions and that the balance of risks and benefits in adults remains positive in their licensed indications. Prescribing should be restricted to those health professionals who have a particular expertise in this area. Randomised studies have now shown that half-cycle SSRI treatment is as efficacious as continuous administration. The results of a recent trial showed that the total premenstrual

scores were lower in the luteal-phase dosing group in each of the three treatment months but the differences were not statistically significant from full-cycle dosing group. Further analysis of each of the symptoms showed significant differences ($P < 0.05$) in favour of luteal-phase dosing for mood swings, nervous tension, feeling out of control and confusion.

The importance of this is that PMS sufferers are less likely to develop dependence on this regimen, benefit is immediate and women are more likely to accept the treatment as it can be regarded as being different from the regimens used for psychiatric disorders. In the author's opinion, the optimum regimens for PMS are half-cycle citalopram or escitalopram, 20mg per day from day 15 to day 28 of the cycle. This regimen appears to be effective even in women whose previous SSRI treatment has failed. Severe PMS also improves significantly with either luteal-phase or symptom-onset dosing of escitalopram with good tolerability.

Recommendation A:

In view of their proven efficacy and safety in adults, SSRIs should be considered one of the first line pharmaceutical management options in severe PMS.

Cognitive Behavioural Therapy

A recent study examined the relative effectiveness of fluoxetine (20 mg daily) and cognitive behavioural therapy (CBT) (ten sessions), and combined therapy (fluoxetine plus CBT) in women with Premenstrual Dysphoric Disorder (PMDD). This was a randomised treatment trial lasting 6 months; follow-up was undertaken 1 year post-treatment. Significant improvement occurred in all three treatment groups after 6 months of treatment. Fluoxetine was associated with a more rapid improvement but at follow-up, CBT was associated with better maintenance of treatment effects compared with fluoxetine. There appeared to be no additional benefit of combining the treatments and no difference in efficacy between the treatment groups. A clinical psychology service should be available for women with PMS, ideally as part of the MDT.

Recommendation A:

When treating women with severe PMS, cognitive behavioural therapy should be considered routinely as a treatment option.

CONCLUSIONS

PMS continues to be poorly understood and in many cases inadequately managed. It can be the cause of considerable morbidity and at times even mortality. It is imperative that a consensus on definition is reached globally and that properly conducted research continues to be funded. It is only through this work that clinicians will be able to practise in a truly evidence-based way to treat effectively this condition.

The alternatives to traditional therapy, such as Agnus Castus, Red Clover and St John's Wort, are showing promising results in randomized controlled studies but more data are needed. The data

on natural progesterone remain controversial, although many women appear to derive considerable benefit from being on this preparation. Progestogens should not be used as they are very good at reproducing the symptoms of PMS. The more established therapies for which randomized controlled data exist are the combined third generation pills (esp. Yaz), transdermal oestradiol, selective serotonin re-uptake inhibitors and the GnRH analogues. Hysterectomy with bilateral salpingo-oophorectomy and adequate hormone replacement therapy remains an option for the severely afflicted woman whose family is complete and has not responded fully to other therapies.

KEY REFERENCES / FURTHER READING

National Association for Premenstrual Syndrome: Advice for sufferers and health professionals. Web address:

www.pms.org.uk

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2. Panay N. Management of Premenstrual Syndrome. *Journal of Family Planning and Reproductive Health care* 2009; 35(3):187-194.
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5. RCOG Green Top Guideline No 48 The management of Premenstrual Syndrome Ed. Panay N Dec 2007 www.rcog.org.uk
6. Dr Farah Ahmed and Dr Emma Cordle, *Coping with PMS*, Sheldon Press 2009

Key to Superscripts

* Few treatments for PMS are actually licensed – the treatments with an asterisk are ones for which sufficient evidence exists for a GP with an interest in women's health to prescribe reasonably from a medico legal point of view.

OTC - over the counter medications

IE – not recommended, insufficient evidence for efficacy

IS – not recommended, insufficient evidence for safety

Classification of evidence levels

- Ia Evidence obtained from meta-analysis of randomised controlled trials.
- Ib Evidence obtained from at least one randomised controlled trial.
- IIa Evidence obtained from at least one well-designed Controlled study without randomisation
- IIb Evidence obtained from at least one other type of well-designed quasi-experimental study.
- III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.
- IV Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Grades of recommendations

A

Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendations (Evidence levels 1a, 1b)

B

Requires the availability of well-controlled clinical studies but no randomised clinical trials on the topic of recommendations. (Evidence levels IIa, IIb, III)

C

Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)

Good practice point



Recommended best practice based on the clinical experience of the guideline development group.

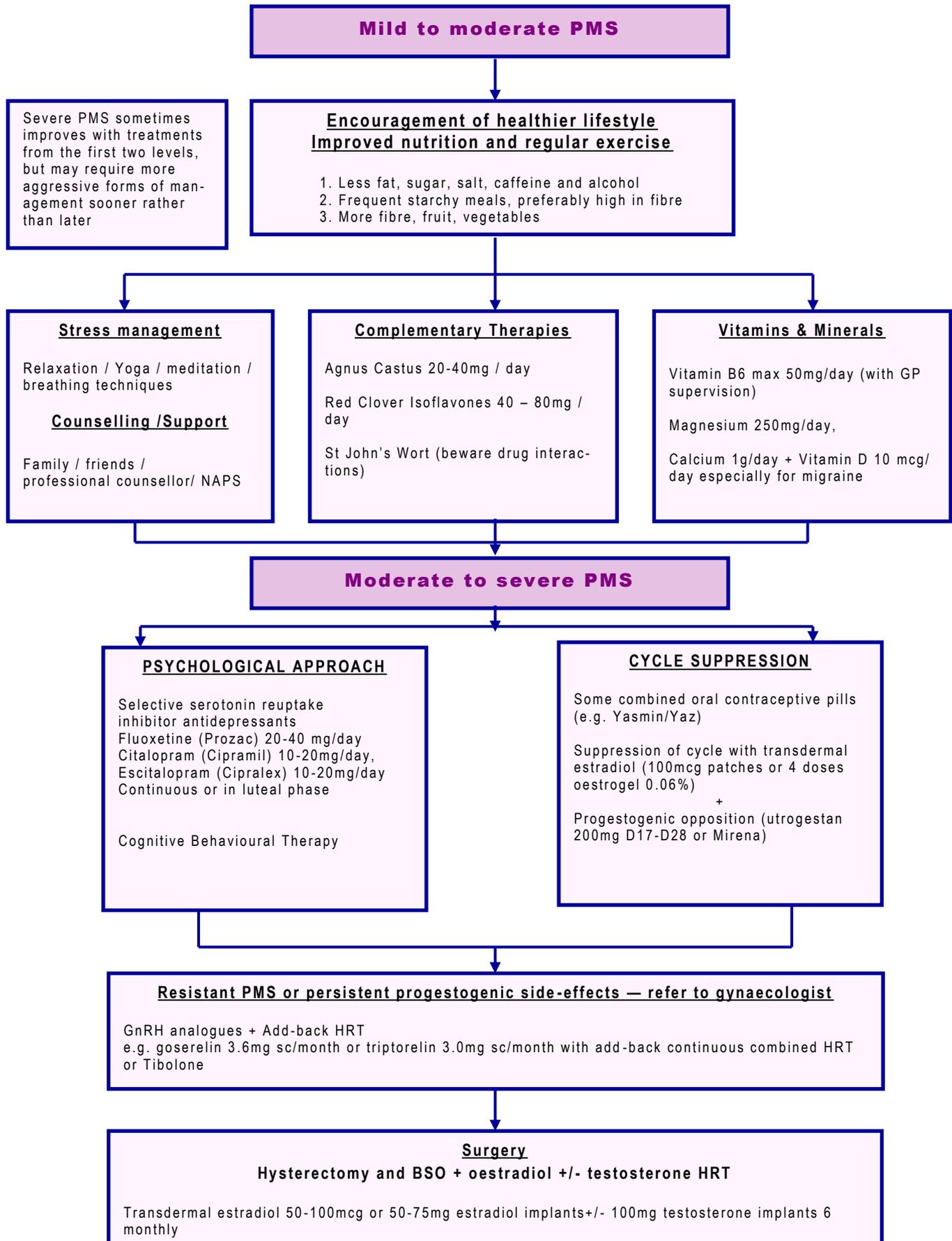
Definitions of the different types of premenstrual syndrome

Type	Definition
Mild	Does not interfere with personal/social and professional life
Moderate	Interferes with personal/social and professional life but still able to function and interact, although may be suboptimally
Severe	Unable to interact/socially/professionally-withdraws from social and professional activities (treatment resistant)
Premenstrual exaggeration	Background psychopathology, physical or other condition with incomplete relief of symptoms when menstruation ends
Premenstrual Dysphoric Disorder	This is a research criteria, not in general use outside the USA. This definition of severe PMS has been adopted by the American Psychiatric Association

Treatment guidelines for PMS

Nick Panay BSc MRCOG MFSRH

Chairman of the National Association for Premenstrual Syndrome, Director of West London Menopause & PMS Centre, Consultant Gynaecologist Imperial College Healthcare NHS Trust & Chelsea and Westminster NHS Foundation Trust, Honorary Senior Lecturer, Imperial College London





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**41 Old Road, East Peckham,
Kent
TN12 5AP**

Patients can contact NAPS for
information and support at:

www.pms.org.uk

0844 815 7311

or at the above address



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