

**AN OBSERVATIONAL STUDY ON THE EFFICACY OF INDIVIDUALISED
HOMEOPATHIC TREATMENT ON PREMENSTRUAL SYNDROME IN INDIAN
FEMALES**

A research dissertation presented to the Faculty of Health Sciences, University of Johannesburg, as
partial fulfilment for the Masters Degree in Technology Homoeopathy by:

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Abstract

Premenstrual Syndrome (PMS) is a group of physical, mental and behavioural symptoms that occur cyclically through the luteal phase of the menstrual cycle and resolve within three days of the onset of menstruation (Delera *et al.*, 2012). More women are affected by the physical and psychological symptoms of premenstrual syndrome than any other condition. A study done by Brohi *et al.* (2011) showed that PMS is a common problem that occurs in 81.25% of women and has an adverse impact on a woman's quality of life. The symptoms of PMS can change the behavior and wellbeing of women which has an impact on families, social life and work (Campagne and Campagne, 2007). Research has shown that women with PMS reported additional days missed from work compared to women that do not suffer with PMS (Lustyk and Gerrish, 2010). A study done by Brohi *et al.* (2011) showed that PMS is a common problem that occurs in 81.25% of women and has an adverse impact on a woman's quality of life. Conventional treatment is limited, not always effective and is associated with many side effects (Zaka and Mahmood, 2012). Research using individualised homeopathic treatment in PMS has been shown to be effective (Yakir *et al.*, 2001), however there have not been any studies done on homeopathic treatment in Indian females in South Africa.

The aim of this observational study was to determine the efficacy of individualised homeopathic treatment on females of Indian origin in South Africa who were suffering with symptoms of PMS using case studies and a PMS grading chart.

This was a 12 week individualised homeopathic study conducted at the Homeopathic Health Training Centre on the UJ Doornfontein Campus. South African Indian females between 18-40 years of age were recruited using advertisements in the form of posters. Ten South African Indian females participated in this study. Each participant attended a total of four consultations over a 12 week period. During the first consultation the researcher explained the study to the individuals who met the criteria based on the selection questionnaire, they were then requested to sign the Participant Information and Consent Form. A full case history was taken using a standard homeopathic case taking form. Participants were required to score their daily symptoms on a PMS chart from the beginning of each menstrual cycle until the beginning of the next cycle. A baseline of each participant's premenstrual symptoms was established by an initial treatment free month. During the follow up consultations (week 4, 8 and end of week 12) the PMS charts were collected, and a case taking and relevant physical examinations were completed. At the end of the consultation in week 4

and 8 an individualised homeopathic remedy was prescribed. At the final consultation (week 12) no remedy was prescribed. Remedies were dispensed in number eight vials by the Homeopathic Health Training Centre.

Data collected and analysed from the PMS grading chart was statistically and graphically presented using the Friedman test to compare the severity of symptoms experienced in the premenstrual period (14 days before menstruation) the baseline symptoms recorded in the initial treatment free period for each symptom over the 2 month treatment period. Wilcoxon Signed Ranks test was done to determine where the differences had occurred (Van Staden, 2013).

The individualised homeopathic remedy showed statistically significant improvements (P values < 0.05) when using Friedman test results for the following symptoms: irritability (P=0.000), depression (P=0.033), breast swelling (P=0.004), headaches (P=0.013) and food cravings (P=0.004) over the two month treatment period. However the individualised homeopathic remedy showed no significant improvement (P values > 0.05) in the following symptoms: anxiety (P=0.602), breast tenderness (P=0.360), abdominal bloating (P=0.058) and swelling of extremities (P=0.072) over the 2 month treatment period. However, research for a longer study period and larger study sample should be conducted before any definitive conclusions can be drawn.

Introduction

Definition

Premenstrual syndrome (PMS) is a broad term which includes a group of emotional, behavioural and physical symptoms that occur in the luteal phase of the menstrual cycle and subside in the follicular phase of the menstrual cycle (Freeman, 2003).

Symptoms

There are many symptoms that can occur during PMS. These include emotional, physical and behavioural symptoms. Emotional symptoms include: irritability, mood swings, anxiety, depression and a feeling of being out of control. Physical symptoms include: swelling, breast tenderness, headaches, bloating and weight gain. Behavioural symptoms include: sleep disturbances, appetite changes, poor concentration, decreased interest in activities and social withdrawal (Freeman, 2003).

Aetiology of PMS

The aetiology of PMS is unknown and can be considered to be multifactorial (Oats and Abrahams, 2012). Factors that contribute to the aetiology of PMS include: genetics, the interaction of cyclical changes in oestrogen and progesterone; adrenalin, allopregnanolone and prolactin; neurotransmitters, including serotonin and gamma amino butyric acid (GABA); diet and lifestyle factors (Zaka and Mahmood, 2012).

Epidemiology of PMS

Epidemiological surveys have estimated that because of the different measurement tools or diagnostic criteria that have been used previously to assess PMS, up to 75% of women who are of a reproductive age experience symptoms of PMS (Kleinstaubler et al., 2012). Studies conducted showed that the prevalence of moderate PMS ranges from 13.4% to 34.1%. Currently, it is cited that about 3–9% of women report having a severe type of PMS which is identified as PMDD this is sufficient for females to seek treatment (Wang et al., 2012).

Diagnosis of PMS

The American College of Obstetricians and Gynaecologists (ACOG) published diagnostic guidelines in the year 2000 (there are no updated versions available) for PMS. The ACOG diagnostic criteria requires at least:

- One physical symptom (breast tenderness, breast swelling, abdominal bloating, headaches, swelling of extremities or food cravings)
- One mental symptom (irritability, depression or anxiety)
- Should occur five days before menses
- In each of the three prior cycles, and
- An amelioration of the above symptoms within four days of the onset of menses.
- These symptoms should not return until at least day thirteen of the cycle and
- Should also be associated with an impairment or dysfunction in social or economic performance (Halbreich, 2004).

There are no objective tests for the diagnosis of PMS, however using a PMS diary helps to determine if there is a symptom-free period after menstruation, as well as to exclude another cause or illness (Edmonds, 2012). For clinical purposes, a PMS chart is suitable to recognise and track symptoms and their timing. Symptoms should be confirmed by doing a daily rating for at least two consecutive cycles (Indusekhar *et al.*, 2007).

Differential diagnosis of PMS

The differential diagnosis of PMS can be divided into medical and psychiatric disorders. Medical disorders include: premenstrual dysphoric disorder, dysmenorrhea, hypothyroidism, autoimmune disorders, seizure disorders and endometriosis. Psychiatric disorders include: major depression, dysthymia, generalised anxiety, panic and bipolar illness (Freeman; 2003).

The impact of PMS on the Quality of Life (QOL)

One study conducted on the frequency and impact of PMS, on the QOL of women of reproductive age by Brohi *et al.* (2011) showed that a very high frequency (81.25%) of women suffered with PMS and it had an impact on their QOL. A study was conducted at a University in Egypt on the knowledge and practice of female employees and the effects of PMS on their daily activities. It was found that PMS was associated with difficulty concentrating at work, decreased work production, increased work absence and being late for work (El-Hamid *et al.*, 2013). Another study conducted in Tehran on the effect of PMS on the QOL in adolescent girls found that PMS affected the girls by reducing their quality of mental health and vitality (Taghizadeh *et al.*, 2008).

Conventional treatment for PMS

Conventional treatment can be categorised in four ways: hormonal, psychotherapeutic, diuretics and surgical (Oats and Abrahams, 2012). However these conventional treatments have a limited efficacy and many side effects (Zaka and Mahmood, 2012).

Hormonal treatments

Oestrogen

There is proof that the suppression of ovarian function using oestrogen removes PMS (Usman *et al.*, 2008). Oestrogen can be administered in different forms such as the oral contraceptive pill (OCP), conventional cyclical or continuous hormone replacement therapy (HRT), and oestradiol patches or implants. Women that are receiving unopposed oestrogen will require progestogen locally in the form of levonorgestrel releasing intrauterine systems in order to protect the uterus from the untoward side-effects of unopposed oestrogen: depression, tiredness, bloating and increased risk of uterine cancer. This reduces systemic absorption of oestrogen and prevents the re-introduction of premenstrual symptoms (Elovainio *et al.*, 2007).

Combined OCP

The combined OCP (COCP) works by suppressing ovulation by inhibiting the secretion of GnRH through the combined activity of both the oestrogen and progesterone components of the hypothalamic-pituitary ovarian axis. COCP causes a new progesterone cycle to be introduced. Trials have shown conflicting results. While some trials have shown that the COCP was ineffective in the treatment of PMS, other trials have shown that while the COCP lessened the physical symptoms of PMS, they do not improve mental symptoms. It must also be noted that the adverse effect of COCP includes negative mood symptoms similar to that of females that suffer with PMS (Halbreich *et al.*, 2006).

Progesterone and progestogen

Progesterone (natural progesterone) and progestogen (synthetic progesterone) can be administered in the form of pessaries, injections, vaginal gel, or orally using the micronised form. The use of progesterone in the management of PMS has been done on an unsubstantiated basis that progesterone deficiency is the cause of PMS symptoms. Progestogens such as dydrogesterone and norethisterone have been shown to be clinically ineffective in randomised control trials (RCTs)

conducted on participants with PMS; and were shown to cause PMS when given as part of HRT. The side effects of progesterone or progestogen depend on how they are administered, however side effects include abdominal pain, nausea, headache, dizziness and dysmenorrhea (Salamat *et al.*, 2007).

Synthetic steroid ethisterone (Danazol)

Danazol is a synthetic steroid male hormone (androgen derivative) that works by preventing ovulation and stops ovarian function. If it is given during the luteal phase of the menstrual cycle it has been shown to be ineffective for most symptoms of PMS (Rosolowich *et al.*, 2006). The side effects of the Danazol include mood swings, nausea, dizziness, rashes, headaches, masculinization and mastalgia which occurs cyclically (Glenville, 2002). Danazol is seldom used now, but if it is, small doses are advised, and careful counseling should be given regarding contraception, because danazol can cause virilisation of a developing female fetus (Nevatte *et al.*, 2013).

Gonadotropin releasing hormone (GnRH) analogues agonists

GnRH agonists work by suppressing ovarian function and are extremely effective in the treatment of PMS. GnRH agonist analogues appear to offer a significantly higher therapeutic effect compared to progesterone and progestogen however it induces 'menopausal' side effects and possible complications from long term use such as osteoporosis and an increased risk of cardiovascular disease (Wyatt *et al.*, 2004), other side effects include hot flushes, vaginal dryness, occasional depression, headaches and muscle aches (Rapkin, 2003).

Bromocriptine

Bromocriptine is a dopamine agonist. It has the ability to decrease the levels of prolactin. Bromocriptine has been shown to be effective in the treatment of premenstrual mastalgia. Some studies have also shown that bromocriptine improves symptoms such as swelling, bloating, weight gain, depression, insomnia, anxiety and irritability; however, this has not been shown consistently across studies (Usman *et al.*, 2008).

Psychotherapeutic treatment

Anti-depressants

Psychotherapeutic treatment includes serotonergic and non-serotonergic antidepressants. Serotonergic antidepressants are known as Selective serotonin reuptake inhibitors (SSRIs). SSRIs prevent the brain from re-absorbing serotonin and are beneficial in the treatment of anxiety and depression associated with PMS (Steiner *et al.*, 2006). Adverse side effects of SSRIs include gastrointestinal symptoms such as anorexia, nausea, weight loss; nervousness; insomnia and sexual dysfunction (Salamat *et al.*, 2007). Non-serotonergic antidepressants are less effective than SSRIs and no more effective than placebo in the treatment of PMS (Nevatte *et al.*, 2013). Adverse side effect of non-serotonergic antidepressants include gastrointestinal bleeding, colitis, headaches, dizziness, nervousness, hypersensitivity skin reactions, tinnitus, edema, depression, drowsiness, insomnia and impaired renal function (Snyman, 2007).

Anxiolytics

Anxiolytics act on the central nervous system and can be therefore potentially used for premenstrual insomnia, anxiety/tension and irritability. However treatment with anxiolytics should be monitored carefully especially in individuals who have a history of substance abuse, because not enough research has been done on anxiolytics for PMS due to a risk of drug dependence (Nevatte *et al.*, 2013).

Diuretics

Diuretics are aldosterone receptor antagonists. Diuretics such as Spironolactone are steroid drugs which treat certain types of edema by promoting the excretion of sodium. In women who experience premenstrual water retention, a small dose of 25–50 mg/d of Spironolactone has produced positive effects on breast tenderness and bloating (Salamat *et al.*, 2007). A study done showed that taking 100mg of Spironolactone daily from day five until day twenty five of the menstrual cycle did not show any improvement of either the physical and psychological symptoms compared to placebo (Halbreich *et al.*, 2006). Some of the adverse effects of Spironolactone include gastrointestinal disturbance and menstrual irregularities, which may be substantial enough for a patient to stop the treatment (Salamat *et al.*, 2007).

Surgery

A bilateral oophorectomy or a total hysterectomy are extreme treatment options for PMS and is not recommended (Oats and Abrahams, 2012) as it is invasive and seldom justified, however it may be used in extreme circumstances (Usman *et al.*, 2008). This procedure will cause premature menopause and PMS symptoms will be replaced with menopausal symptoms (Glenville, 2002).

Complementary treatment for PMS

Complementary treatments for PMS include diet and exercise, nutritional supplements, phytotherapy, cognitive behavioural therapy, traditional Chinese medicine, reflexology and homeopathy.

Diet and exercise

RCTs show that increasing the amount of complex carbohydrates during the luteal phase of the menstrual cycle decreases the severity of PMS, especially the mood symptoms. Reducing caffeine, salt, refined sugars and alcohol may help reduce PMS; however no trials have been conducted (Bahamondes *et al.*, 2007).

Premenstrual symptoms have been shown to be less in females who do sporting activities regularly. A study was conducted on females who lead a sedentary lifestyle who were then introduced to exercise and were monitored prospectively for 6 months. Results showed an improvement in mood symptoms, fluid retention and breast tenderness associated with PMS (Salamat *et al.*, 2007). A large survey on 1,800 females found that exercise was used by more than half of the women as a self-help measure, where over 80% found it helpful for alleviating PMS symptoms (Girman *et al.*, 2003). Aerobic exercise was found to improve symptoms of PMS; however this was only in one small randomised trial (Bahamondes *et al.*, 2007).

Nutritional supplements

Calcium and Vitamin D

Calcium is the dietary supplement with the strongest empirical support of alleviating premenstrual symptoms (Whelan *et al.* 2009). Calcium supplementation has been shown to decrease premenstrual symptoms by as much as 30% (Balch and Balch, 2003; Bendich, 2013). A study showed that supplementing 1200 mg of calcium daily decreased the total symptom score of PMS by 48%

compared to 30% in the placebo group (Canning *et al.*, 2010). Some studies have shown that blood calcium and vitamin D levels are lower in women with PMS (Panay, 2011). Increasing the levels of calcium during menstruation is theorised to control calcium homeostasis before ovulation. However more trials need to be conducted (Nevatte *et al.*, 2013; Panay, 2011).

Vitamin B6 (pyridoxine)

Vitamin B6 is important for amino acid and fatty acid metabolism. It is important for normal nerve functioning and for the formation of red blood cells (Beers *et al.*, 2003). It also plays a role in synthesising certain neurotransmitters which control behavior and mood such as depression (Glenville, 2002). A systemic review of studies suggested that a dose of 100 mg daily of vitamin B6 could be beneficial for the symptoms of PMS including depression, however conclusions are limited. A dosage of more than 100 mg of vitamin B6 daily has been associated with neurotoxicity (Colledge *et al.*, 2010).

Vitamin E

A study was done to evaluate the effects of vitamin E supplementation in women with PMS; participants received 400 IU/day of vitamin E or placebo for three menstrual cycles. Significant improvements in certain emotional and physical symptoms were observed in the vitamin E group and there was no effect seen in the placebo group. More studies need to be conducted to determine the efficacy of vitamin E (Bendich, 2013). Adverse effects of Vitamin E (more than 1200 I/U per day) include flatulence, nausea, heart palpitations and diarrhea (Integrative Medicine, 2000). Vitamin E should also be taken with caution in patients taking anticoagulant medication, or who have diabetes, rheumatic heart disease, hyperthyroidism or high blood pressure (Balch and Balch, 2003).

Magnesium

Magnesium supplementation has been shown to help with symptoms of PMS such as, premenstrual migraine headaches and dysmenorrhea. Females that suffer with PMS have been shown to have low red blood cell magnesium levels compared to females without PMS (Rosenstein *et al.*, 1994). Taking 200-400 mg of magnesium daily has been shown to be effective in the treatment of PMS (Bahamondes *et al.*, 2007), specifically for fluid retention and mood. A pilot study done on the efficacy and safety of 250 mg modified-release magnesium was effective in decreasing premenstrual

symptoms in women with PMS (Quaranta *et al.*, 2007). A possible side effect of doses greater than 10 mg per kg per day (e.g. 700 mg Magnesium in a 70 kg person) is osmotic diarrhea (Bendich, 2013).

Essential fatty acids (EFAs)

A deficiency in the metabolism of fatty acids has been found in females suffering with PMS. Evening primrose oil contains the fatty acids linoleic acid and gamma linoleic acid. A randomised controlled study showed efficacy for an EFA preparation that contained linoleic acid, gamma-linoleic acid, oleic acid and vitamin E in improving premenstrual symptoms compared to the placebo (Rocha Filho *et al.*, 2011). However previous studies on evening primrose oil for the treatment of PMS did not show it to be superior to placebo (Campagne and Campagne, 2007).

Phytotherapy

Vitex agnus castus (Chaste berry/Chaste tree)

Vitex agnus castus works by inhibiting the secretion of prolactin. *Vitex agnus castus* has been shown to decrease symptoms such as irritability, depression, anxiety, rage, headache, desire for sweets and breast swelling associated with PMS by 50% and more (Berger *et al.* 2000; Loch *et al.* 2000; Schellenburg, 2000). Studies comparing fluoxetine and vitamin B6 with *Vitex agnus castus* in decreasing premenstrual symptoms showed no significant difference (Atmaca *et al.*, 2003; Zamanil *et al.*, 2012). Adverse effects of *Vitex agnus castus* mainly affect the gastrointestinal tract, skin, and the integumentary system (Loch *et al.*, 2000). *Vitex agnus castus* is not safe to use during pregnancy (Bendich, 2013).

Hypericum perforatum (St. John's wort)

Hypericum perforatum has been proven to be effective in the treatment of mild to moderate depression in some studies (Canning *et al.*, 2010; Clement *et al.*, 2006). However according to one study, *Hypericum perforatum* did not reduce premenstrual depression compared to placebo (Hicks *et al.*, 2004). Adverse effects of *Hypericum perforatum* include abdominal pain, constipation, bloating, nausea, vomiting, dizziness, dry mouth, itching, hives, skin rashes, sleep problems, unusual tiredness, photosensitivity and elevated blood pressure (Integrative medicine, 2000).

Matricaria chamomila (Chamomile)

A clinical randomised double blinded study was conducted to compare the effects of 100 mg *Matricaria chamomila* to a non-steroidal anti-inflammatory drug (NSAID) in women with PMS. There was a decrease in emotional symptoms among *Matricaria chamomila* users in comparison to NSAID's after two cycles. However the physical symptoms were not significantly different among either group. *Matricaria chamomila* seems to be more effective than NSAIDs in relieving the intensity of premenstrual related psychological pains; however more studies need to be done to confirm the efficacy of Chamomile extract (Sharifi *et al.*, 2014).

Dioscorea villosa (Wild yam)

Wild yam root contains diosgenin, which is a substance that is used in laboratory synthesis of steroid hormones. The use of Wild yam in the treatment of PMS is based on the reasoning that diosgenin will be converted into progesterone in the body, and this may relieve premenstrual symptoms. However, the conversion of diosgenin to progesterone has been proven only *in vitro* and not in the human body. The effect of wild yam root in women with PMS is not known (Bendich, 2013).

Ginkgo biloba (Ginkgo)

Ginkgo biloba extract contains active compounds including flavonoids and terpenoids. Terpenoids have antioxidant and scavenging properties. *Ginkgo biloba* inhibits platelet-activating factor has anti-inflammatory effects and also relaxes vascular smooth muscles. A study done on *Ginkgo biloba* showed a statistically significant improvement in all the premenstrual symptoms, especially breast tenderness and fluid retention (Ozgoli *et al.*, 2009). However *Ginkgo biloba* works by inhibiting platelet-activating factor; and could increase chances of bleeding in some people (Ozgoli *et al.*, 2009; Girman *et al.*, 2003).

Cognitive Behavioural Therapy (CBT)

CBT for PMS involves adaptive ways of coping with PMS. CBT is used in the treatment of mild to moderate PMS with no adverse effects. Studies have shown that CBT decreases anxiety, depression, negative thoughts and physical symptoms but it may be expensive (Bahamondes *et al.*, 2007). In another study conducted by Hunter *et al.* (2002) it was shown that CBT was as effective as

fluoxetine (SSRI) in the treatment of anxiety associated with PMS. More controlled studies need to be conducted to support the efficacy of CBT (Campagne and Campagne, 2007).

Reflexology

Reflexology uses manual pressure on certain reflex points such as the ears, hands, and feet, that somatotopically correspond to specific areas of the body. A randomised controlled study evaluated the effect of reflexology therapy on the symptoms of PMS. Women that received true reflexology showed a considerable decrease in PMS symptoms compared to placebo reflexology (Girman *et al.*, 2003).

Traditional Chinese Medicine (TCM) and Acupuncture

Traditional Chinese medicine (TCM) targets both psychological and physical symptoms. Dong quai (*Angelica Sinensis*) is a TCM herb that is frequently called 'female ginseng'. It encourages normal hormonal balance and is also used for cramping and pain associated with PMS (Laister, 2008). Dong quai also acts as a mild sedative, laxative, diuretic, antispasmodic and therefore a pain reliever. It also assists the body to use hormones (Balch and Balch, 2003). TCM is effective when used in conjunction with other therapies, however further research is required in its treatment of PMS (Chou and Morse, 2005). Studies conducted comparing acupuncture to TCM and hand acupuncture therapy with hand moxibustion showed that there was an improvement of the primary symptoms of PMS (Fang *et al.*, 2008; Shin *et al.*, 2009; Xu and Sun, 2006). Acupuncture is generally regarded as being safe. Potential side effects of acupuncture include pain caused by needling, hematoma formation, bleeding, orthostatic problems, pneumothorax, spinal lesion and infection (Cho and Kim, 2010).

Homeopathy

Individualisation

Prescribing homeopathic remedies accurately depends on the correct match between the homeopathic remedy (similimum) and the individual characteristics of the illness in the patient. This treatment is said to be individualised, where the individual is considered on a mental, physical and emotional level in a holistic way, using the principles of classical homeopathy (Swayne, 1998).

Simillimum Prescribing

The homeopathic simillimum refers to the unique, individualised homeopathic remedy that covers the totality of symptoms experienced by the individual being treated (De Schepper, 2011). In order to determine the homeopathic simillimum it requires extensive case taking which involves an in-depth interview to obtain as much information as possible based on the individuality of the patient; the case is then analyzed to help find the simillimum (Subramanian and Subramanian, 2004). The Homeopathic repertory originates from the Latin word “Repertorium” which means “place for finding something, table or compendium where the contents are arranged in such a way that they are easy to find” (Sydow, 1997). Finding the simillimum requires that the symptoms must be graded and grouped correctly. This is done by taking symptoms from the patient and comparing them to the symptoms (rubrics) found in the repertory (Jayasuriya, 2005).

Potency selection and the repetition of the dose of the homeopathic remedy are individually applied in accordance with De Schepper’s method of prescribing to integrate the condition, remedy and the individual patient (De Schepper, 2010).

Materials and method

Research design

The research design was in the form of descriptive case studies using individualised homeopathic treatment for PMS. The case studies were analysed and described over time.

Research sample

Using purposive sampling, ten South African Indian females between 18-40 years of age who experienced PMS symptoms were recruited using advertisements in the form of posters which were placed with permission granted from those in authority on notice boards on the UJ campuses, health stores and at various homeopathic/medical practices.

Potential participants had to complete a selection questionnaire and were selected according to the following criteria:

Inclusion criteria

Participants were included in the study if they:

- Are females between the ages of 18 and 40 years who experienced PMS on a monthly basis;
- Experienced an increase in at least one of the following mental and physical symptoms at least 14 days before their menses began, in each of the three preceding menstrual cycles:
 - Mental symptoms-irritability, depression or anxiety
 - Physical symptoms-breast tenderness or swelling, abdominal bloating, headaches, swelling of extremities or food cravings; and
- Have an amelioration of the above symptoms within three days of the onset of menses and symptoms should have not reoccurred until at least day 13 of their cycle.

Exclusion criteria

Participants were excluded from the study if they:

- Had irregular menstrual cycles;
- Were lactating females;
- Were pre-diagnosed with anxiety and depression;
- Used sex hormones except the oral contraceptive (must have been used for a minimum of 3 months);
- Had concomitant psychotherapies and/or alternate therapies for PMS; and/or
- Were pregnant.

Participants were asked not to make use of any homeopathic remedies, herbal supplementation, acupuncture or any other treatment for PMS or make any changes to their lifestyle or diet while participating in this study. If participants were using any conventional medication or if there had been any changes in their dosage or brand of oral contraceptive they were requested to document this in the questionnaire.

Method

In this three month case study, ten participants were required to complete a PMS chart, which graded the severity of PMS symptoms on a daily basis until their next menstrual cycle. They also were required to note down the dates of menstruation. A baseline of each participant's premenstrual symptoms was established by an initial treatment free month. Participants were treated using individualised homeopathic treatment for the remaining two months. The evaluation of the

symptoms in the PMS chart was subjective and was based on a 5 point scale where 0 - “no symptom”, 1- “very mild”, 2 - “mild”, 3 - “severe”, 4 - “extremely severe.

Data collection and analysis

Data collected from the observational studies and the PMS chart were analysed, where changes in the totality of symptoms were described over time using descriptive and graphical representation.

Results and discussion

In order to test the hypothesis non-parametric Wilcoxon signed ranked test and Friedman test were used. The P-values were determined between each premenstrual phase of the menstrual cycle during the three month study period (Van Staden, 2014).

The individualised homeopathic remedy showed statistically significant improvements (P values < 0.05) when using Friedman test results for the following symptoms: irritability (P=0.000), depression (P=0.033), breast swelling (P=0.004), headaches (P=0.013) and food cravings (P=0.004) over the two month treatment period.

The individualised homeopathic remedy showed no significant improvement (P values > 0.05) in the following symptoms: anxiety (P=0.602), breast tenderness (P=0.360), abdominal bloating (P=0.058) and swelling of extremities (P=0.072) over the 2 month treatment period. The following may be the reason why there were no statistically significant improvements in the above symptoms:

- The time at which the study was done was between the months of August and December. This was a very stressful period for many of the participants. Many of them were in stressful professions such as educators or had exams such as the students. This could have had an effect on their anxiety levels.
- The study treatment period was only 2 months. This time frame might have been too short to notice a statistically significant effect of the homeopathic remedies on PMS symptoms. Certain participants only started seeing improvements after month 2 of treatment and a longer time period could have produced better results.
- The frequency or potency of the homeopathic remedy may have not been prescribed often enough.

- There might have been a need to re-evaluate certain cases and change the homeopathic remedy.
- Abdominal bloating and swelling of extremities could be caused by diet and lifestyle factors and not only PMS.

Conclusion

The homeopathic simillimum was statistically significant in reducing the following premenstrual symptoms: irritability (0.000), depression (0.033), breast swelling (0.004), headaches (0.013) and food cravings (0.004) over the two month treatment period.

The homeopathic simillimum showed no improvement in the following premenstrual symptoms: anxiety (0.602), breast tenderness (0.360), abdominal bloating (0.058) and swelling of extremities (0.072) over the 2 month treatment period.

It is recommended that in future studies:

- The potency and frequency of the remedy could be reevaluated and increased or decreased in accordance to the principles of homeopathic prescribing depending on the participant's symptoms. In some cases the potency could have been too low and yield poor results.
- If only a few symptoms had improved and the remedy no longer seemed well indicated then the case should have been reevaluated.
- The study should be conducted at the beginning of the year, to avoid stressful periods such as exams.
- A larger sample group should be considered in order to yield better results statistically.
- A longer study period should be used as simillimum studies are usually conducted over several months in order to yield better results and observe changes over a longer period of time.
- A study to compare the effects of diet and lifestyle on PMS would be useful and could be part of a comparison with the efficacy of homeopathic treatment.

Together with Komar (2005), Patel (2010) and Mainganye (2011) the following recommendations can be followed to improve subsequent research:

- A larger sample group should be considered as this could yield better results.

- A double blinded study comparing individual homeopathic treatment and placebo group would be useful in order to compare the results of participants receiving placebo versus those that are receiving the homeopathic treatment.
- A study comparing homeopathic simillimum treatment to a complex homeopathic remedy, to compare each person's response to different methods of homeopathic prescribing.
- If the remedy seems well indicated it should not be changed because the patient may be close to cure and the wait and watch approach should be used if necessary.
- The frequency and dosage should not be changed with haste and a wait and watch approach should be used if necessary.

Acknowledgements

This study was conducted by the author under the supervision of the supervisor Dr Patel and co-supervisor Dr Peck in partial fulfilment for the Master's Degree in Technology: Homoeopathy. The author would like to thank Dr Patel and Dr Peck for their support, encouragement, assistance and advice throughout the conduction and write-up of this study.

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