INTRODUCTION

As women age, their health becomes a multidimensional issue influenced by career, changes in home life, diet and physical activity, economy, society and environment. Lowenthal looking at the plight of menopausal women, coined ‘Empty Nest’ syndrome embracing various factors such as children become independent and leave home with the women facing an isolation; spouse may retire, aged parents may die, social circle gets constricted, marital discord due to altered sexual pace may become manifest, general health declines and woman fears widowhood, economic dependency and death (Lowenthal & Chiribhoga, 1972). Together with these natural processes of ageing, the hormonal changes in the reproductive system may affect the well being of women (Bavadam, 1999).

Although the most striking feature of the menopause is the cessation of menstruation for 12 months (which is a retrospective diagnosis), other biologic and psychosocial events occur many months to years before menopause and can be classified as stressors or facilitators. (El-Guebaly, 1984). Hot flushes and night sweats, considered as primary menopausal symptoms that may also be associated with sleep and mood disturbances as well as decreased cognitive functions may lead to social impairment and work-related difficulties that significantly decrease overall quality of life.

Origin of the problem

The phenomenon of the menopause was known to the ancient Greeks; Aristotle (384–322 BC) described the cessation of menstruation at the age of 40. In the nineteenth century, the menopause was believed to be directly responsible for madness and even in more modern times it has still been believed to cause certain psychiatric illnesses
(Barlow et al, 1997). The word ‘menopause’ is derived from men and pauses and is a direct description of the physiological event in women where menstruation ceases to occur. The word ‘climacteric’ is a Greek derivation of the ‘ladder’ or ‘steps of a ladder’. Over the years, the view of middle-aged women has varied from the extremes of either climbing up or down that ladder (Utian, 1997). Menopausal disturbances have no records until the social convulsions of the French Revolution, and the regimes that followed crystallized the various complaints of climacteric into a disease-expression (Wilbush, 1979). Symptoms associated with the menopause have been known for a long time but it was not until the 1930s that climacteric symptoms could be effectively treated with oestrogen isolated from the urine of pregnant women (Butenandt, 1930). However, treatment was not very widespread until after the publication of Robert A Wilson’s best-selling book Feminine Forever, after which treatment became more popular among physicians and women (Wilson, 1966).

**Prevalence on menopausal problems**

A study was conducted in seven south-east Asian countries. Samples of approximately 400 women in each country were questioned about a number of climacteric complaints. The prevalence of hot flushes and of sweating was lower than in western countries, but was nevertheless not negligible. The occurrence of climacteric complaints affected perceived health status (Sengupta, 2003).

The Indian subcontinent is a mix of many ethnic groups and cultures where perception of menopause varies (IMS, 2003). Since the average life span of women in India has touched 62 years, the problems of menopause have attained a greater significance (WHO, 2003) and are emerging as an issue owing to rapid urbanization.

**Menopause Terminology-Definitions**
Climacteric is a term now used to indicate the physiologic transition characterized by depletion of the ovarian follicles, decreasing inhibin leading to increase in follicle-stimulating hormone (FSH) and loss of the menstrual cycle, accompanied by decreased estradiol production and typical symptoms (Blake, 2006).

The list of menopause-related definitions presented below was approved by the Board of International Menopause Society (IMS) on October 11, 1999, in Yokohama, Japan.

Menopause (natural menopause) – the term natural menopause is defined as the permanent cessation of menstruation resulting from the loss of ovarian follicular activity. Natural menopause is recognized to have occurred after 12 consecutive months of amenorrhea, for which there is no other obvious pathological or physiological cause. Menopause occurs with the final menstrual period (FMP) which is known with certainty only in retrospect a year or more after the event. An adequate biological marker for the event does not exist (IMS, 2003).

Perimenopause – the term perimenopause should include the period immediate prior to the menopause (when the endocrinological, biological, and clinical features of approaching menopause commence) and the first year after menopause (IMS, 2003).

Demographics of perimenopause:

Age of onset is 46 years (95% confidence interval [CI], 39-51)

Average duration is 5 years (95% CI, 2-8)

Ten percent cease abruptly. The perimenopausal transition and mean circulating hormone levels (Gordon & Speroff, 2002).

Climacteric – The phase in the aging of women marking the transition from the reproductive phase to the non-reproductive state. This phase incorporates the perimenopause by extending for a longer variable period before and after the
perimenopause. Climacteric is the period of life characterized by physiological and psychic change that marks the end of the reproductive capacity in women. (IMS, 2003)

Climacteric syndrome – the climacteric is sometimes, but not necessarily always, associated with symptomatology. When the menopausal symptoms accompany climacteric phase, it may be termed as "climacteric syndrome" (IMS, 2003).

Menopause:

12 months of amenorrhoea
LMP ------------------------------- Menopause
(Last menstrual period) (Permanent cessation of menstruation)

Perimenopause:

----- 2 years ----- LMP ----- 2 years ------

Climacteric Syndrome:

---- 2 years ---- LMP -------------- 5 years ------------

Premenopause – The term premenopause is often used ambiguously to refer to the one or two years immediately before the menopause or to refer to the whole of the reproductive period prior to the menopause. The term is used consistently to encompass the entire reproductive period up to the final menstrual period.

Postmenopause – The term postmenopause is defined as dating from the FMP, regardless of whether the menopause was induced or spontaneous.

Premature menopause – Ideally, premature menopause should be defined as menopause that occurs at an age less than two standard deviations below the mean established for the reference population. In practice, in the absence of reliable estimates of the distribution of age at natural menopause in populations in developing
countries, the age of 40 years is frequently used as an arbitrary cut-off point, below which menopause is said to be premature.

Induced menopause – The term induced menopause is defined as the cessation of menstruation which follows either surgical removal of both ovaries (with or without hysterectomy) or iatrogenic ablation of ovarian function (e.g. by chemotherapy or radiation) (WHO, 2003).

<table>
<thead>
<tr>
<th>Final menstrual period (FMP)</th>
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<tr>
<td>Menopause transition</td>
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<table>
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<tr>
<th>Perimenopause</th>
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<td>12 months</td>
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Changes in menstrual cycle at the approach of the menopause:

<table>
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<tr>
<th>Age group length (years)</th>
<th>Follicular phase (days)</th>
<th>Luteal phase (days)</th>
<th>Total cycle (days)</th>
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<tbody>
<tr>
<td>18 – 30</td>
<td>16.9 ± 3.7</td>
<td>12.9 ± 1.8</td>
<td>30.0 ± 3.6</td>
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<tr>
<td>40 – 41</td>
<td>10.4 ± 2.9</td>
<td>15.0 ± 0.9</td>
<td>25.4 ± 2.3</td>
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<tr>
<td>46 – 50</td>
<td>8.6 ± 2.8</td>
<td>15.9 ± 1.3</td>
<td>23.2 ± 2.9</td>
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(Treolar et al, 1967)

Changes in circulating hormone levels at menopause

<table>
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<th>Premenopause</th>
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<th>Postmenopause</th>
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| Estradiol pg/ml | 40 to 4000 pg/ml | 10 to 20 |
| Estrone pg/ml   | 30 to 200 pg/ml  | 30 to 70 |
As women come closer to the menopause, menses frequently become irregular and in general less frequent bleeding which reoccurs after 12 months of amenorrhoea in the perimenopausal years may be due to renewed follicular activity. When women are in their 40s, anovulation becomes more prevalent. Prior to anovulation, menstrual cycle length increases, beginning 2-8 years before menopause. At the same time, fewer follicles grow during each cycle until eventually the supply of follicles is depleted (Copeland, 1993). Shortly after menopause, no follicles remain. Follicle stimulating hormone (FSH) increases 10 to 20 fold and luteinizing hormone (LH) increases 3 fold. Maximum rise occurs at 1 to 3 years after menopause. The postmenopausal ovaries secrete primarily androstenedione and testosterone; most secretion from adrenals and the ovaries respectively (Gordon & Speroff, 2002).

**Vasomotor and somatic symptoms in Perimenopause**

At the time of menopause, some women present a clinical picture of not only the specificity of estrogen deficiency, such as hot flushes, but also a non-specific psychologic syndrome characterized largely by anxiety and depression (Coulam, 1981).

**Etiology of hot flushes**
The pathogenesis of hot flushes has not yet been fully elucidated, but the circuitry involving estrogen and neurotransmitters, norepinephrine and serotonin specifically, are hypothesized to play a major role in the altered homeostatic thermoregulatory mechanisms underlying these events. The neurotransmissive degeneration that follows hypo-estrogenemia, could be responsible for the hot flushes and also the psychological disturbances (Tinelli et al, 2003). The ovarian failure and the termination of reproductive female functions could influence the mental neurotransmission in menopausal women; female menopausal brain, one of the favorite estrogen targets, could suffer a negative homeostasis, affecting the daily behavior (Tinelli et al, 2003). Altered levels of neurotrophic ovarian steroid (17beta-estradiol) have been recognized as one of the factors influencing degenerative processes that lead to aging (Danilovich et al, 2003).

In the female brain, the firing rate of thermo-sensitive neurons in the preoptic area of hypothalamus in response to thermal stimuli is modulated by estrogens. Responsiveness of vascular smooth muscles to vasoactive substances is affected by estrogen. Sudden decrease in estrogen level leads to perturbation of brain’s thermoregulatory center located in hypothalamus. This perturbation activates the mechanism of heat loss (vasodilatation, sweating, behavioral adjustments) followed by heat conservation (vasoconstriction, behavioral changes and shivering) (Urvashi, 2000).

**Psychological symptoms [Mood swings (anxiety, depression)] in menopause**

Perimenopausal women attending menopause clinics have significantly higher levels of psychological distress meeting case severity criteria on the Brief symptom inventory in each of the anxiety, hostility, somatization, depression, paranoid, and psychoticism subscales as compared to menopausal women on the global severity
The cluster "depressive symptoms" was more evident in the postmenopausal period with respect to the premenopausal one where number of life events, postmenopausal status, place of residence in rural areas and lower cultural level were the factors related to pronounce depressive symptoms (Amore et al, 2004).

Hunter (1990) observed that vasomotor symptoms significant increases in depressed mood were more prevalent in peri- and postmenopausal women. Stepwise regression analysis indicated that past depression together with cognitive and social factors accounted for 51 per cent of the variance in depressed mood reported by menopausal women (Hunter, 1990).

**Cross cultural studies**

66 studies organized by geographic region were reviewed and results presented for North America, Europe, East Asia, Southeast Asia, Australia, Latin America, South Asia, Middle East, and Africa. The responses focused on quantitative information on the occurrence of hot flushes and night sweats, the studies indicated that vasomotor symptoms are highly prevalent in most societies. The prevalence of these symptoms varies widely and may be influenced by a range of factors, including climate, diet, lifestyle, women's roles, and attitudes regarding the end of reproductive life and aging (Freeman & Sherif, 2007). Another cohort of 16,065 women aged 40-55 years examined the association between psychologic distress and natural menopause in a community sample of African American, White, Chinese, Hispanic, and Japanese women participating in a national women's health study. Rates of psychological distress associated with irregular menses in midlife (Bromberger et al, 2001), were highest in early perimenopause (28.9%) and lowest in premenopause (20.9%) and postmenopause (22%). In a US sample of 170 menopausal women between ages 45-54, rating menopause as stressful was associated with higher levels of neuroticism,
seeking social support, and avoidance, and lower levels of agreeableness in unadjusted analyses (Bosworth et al, 2003). The perimenopausal depressed women are more likely to report both negative life events and diminished self esteem (Schmidt et al, 2004).

**How are the menopausal problems addressed?**

- **Hormonal therapies:**
  a. Hormone replacement therapy (HRT), Estrogen replacement therapy (ERT), Progesterone replacement therapy (PRT), Continuous combined replacement therapy (CCRT), Selective estrogen progesterone replacement therapy (SEPRT)
  b. Hormonal stimulants like Selective estrogen receptive modulators (SERMs)
  c. Natural hormones – phytoestrogens

- **Non Hormonal therapies:**
  a. Herbs – e. g. black cohosh
  b. Micronutrients – e. g. Iron, Phosphorous
  c. Antioxidants
  d. Calcium
  e. Calcitonin

- **Life style changes & personal habits:**
  a. Exercise and Yoga
  b. Diet – Calcium and iron rich diet
  c. Habits

**Hormone replacement therapy (HRT)**

It was in July 2000 that the National Institute of Health (NIH), USA after observing 16,608 healthy post menopausal women of mean age group of 63.3 years on one
hormone regime (Prempro) for five years, declared that Hormone Replacement Therapy caused small increase in breast cancer, heart attacks, strokes and blood clots. The research which was supposed to run for eight years, was drastically cut short and participants were asked to discontinue their pills, as researchers found HRT boosted a woman’s heart attack risk from 0.3 per cent to 0.37 per cent, stroke rate from 21 to 29 per 10,000 and the breast cancer rose from 30 to 38 per 10,000. The study suggested that a group of 10,000 long-term Prempro users will experience 31 excess health crises, while avoiding only 11 bone fracture and colon cancer. The research created ripples of fear amidst the global scientific community, with few prophesizing the end of era of estrogen (Dutta, 2000). Hormones, once popular, fell from grace in 2002 when a large government study found they increased the risk of blood clots, strokes, heart attacks and breast cancer. HRT Sales plummeted as the number of users dropped to 57 million in 2003 from 91 million in 2001. The article also reports that all the non hormonal drugs give side effects; specifically the antidepressants can cause headache, nausea, dry mouth, dizziness and insomnia or sleepiness (Nicholas et al, 2006). A randomized control study on healthy postmenopausal women who were taking oral 17β estradiol, 2 mg / day for 3 months followed by oral progestagen observed that stress coping did not change after estrogen therapy. The authors expressed that stress coping is an individual propensity and not dependant on specific hormonal status during menopause. Therefore the capacity of coping with stress was not expected to change during HRT. Though the women in the target group got successfully treated for vasomotor symptoms but developed significantly higher neuroticism score compared to the comparison group (Nedstrand et al, 1998). Hormone replacement therapy (HRT), a well known therapy to recover from the cognitive, vasomotor, psychological and autonomic impairments also holds a risk of breast cancer, three-
fold risk of venous thromboembolism and inducing feelings of fear (Russel, 2003). Though estrogen therapy counteracts vasomotor symptoms and is cardio protective but may induce cancer of the endometrium and could contribute to an increase in the incidence of breast cancer in older women (WHO, 1996). WHO declared in Report 2004 that breast cancer kills almost half a million women a year all over the globe (WHO, 2004).

**Need for Complementary and Alternative medicine / Non pharmacological intervention (CAM/NPI)**

Due to the serious adverse effects of HT, there has been gap in the management of menopausal symptoms emphasizing the need to develop and explore the efficacy of alternative therapeutic avenues that have recently demonstrated promise in alleviating menopausal symptoms (Daley et al, 2006). NIH Consensus 2005 declared that there is great need to develop and disseminate information that emphasizes menopause as a normal, healthy phase of women's lives and promotes its demedicalization. Estrogen therapy is highly efficacious in relieving menopausal symptoms and was the treatment of choice until 2002, when findings of unexpected harm from the Women's Health Initiative (WHI) were published. And the WHI study has affected HT usage adversely. Consequently, there has been a burgeoning interest in a number of botanical products as well as other complementary and alternative medicine and behavioural regimens (NIH Consensus, 2005).

Amidst the melee surrounding HRT, the stark reality that hits hard is that HRT is the treatment only for the higher socio-economic class. "The treatment cost ranging from Rs 300 to 500 is out of reach of the lower section of the society. Six out of ten urban women would agree for HRT and none in the lower section go for HRT," says practicing gynecologist, and ex-member, consumer court, Dr Gopinath Shenoy. Dr
Saraiya, agrees with this statement for the Indian scenario and says “HRT cannot replace the calcium that the body needs. For a woman hailing from the lower strata of society, it is better that she concentrates on having a good diet than spending money on HRT” (Dutta, 2001).

**Importance of yoga**

Because many women now want to avoid hormone therapy, there is a need for additional targeted therapies, validated by results from controlled clinical trials that are safe, efficacious, cost-effective, and well tolerated by symptomatic menopausal women (Utian, 2005).

Stress produces a state of physical and mental tension. Yoga, developed thousands of years ago, is recognized as a form of mind-body medicine. In yoga, physical postures and breathing exercises improve muscle strength, flexibility, blood circulation and oxygen uptake as well as hormone functions (Parshad, 2004). Yoga as a complementary and mind body therapy is being practiced increasingly in both Indian and western populations. It is an ancient Indian science that has been used for therapeutic benefit in numerous health care concerns in which mental stress was believed to play a role (Khalsa, 2004). Important facets of a yoga program such as relaxation and mental awareness are known to alter the perceptions, and mental responses to both external and internal stimuli, slow down reactivity and responses to such stimuli and instill a greater control over situations in the participants (Raghavendra et al, 2007).

**Studies on yoga and menopausal syndrome management**

A study chose eight restorative yoga poses for 8 weekly 90-min sessions observed the mean hot flush score decreased by 34.2% from baseline to week 8. This pilot trial
demonstrates that it is feasible to teach restorative yoga to middle-aged women without prior yoga experience. The high rates of subject retention and satisfaction suggest that yoga is an acceptable intervention in this population (Cohen et al, 2007). A 10-week yoga program comprising breathing techniques, postures, and relaxation poses designed specifically for menopausal symptoms, significant pre post treatment improvements were found for severity of questionnaire-rated total menopausal symptoms, hot-flash daily interference; and sleep efficiency, disturbances, and quality (Booth et al, 2007). In a 4-month randomized controlled exercise trial with three arms i.e. walking, yoga and control, it was observed that both walking and yoga were effective in enhancing positive affect and menopause-related QOL and reducing negative affect (Elvasky & McAuley, 2007). Women with emotional distress who participated in a yoga-training demonstrated pronounced and significant improvements in perceived stress, state and trait anxiety, well-being, vigor, fatigue and depression (Michalsen et al, 2005). An Indian study observed remarkable reduction (p<0.001) in the anxiety scores within 10 days of educational programme for lifestyle modification and stress management (Gupta et al, 2006).

**Studies on relaxation techniques for menopause symptoms**

Irvin et al compared the effects of relaxation response and attention-control training in 33 women and found that hot flash intensity and tension-anxiety and depression decreased in the relaxation response group (Irvin et al, 1996). A study examined applied relaxation techniques, which included 12 sessions of progressive relaxation, release-only relaxation, cue-controlled relaxation, differential relaxation, rapid relaxation, application training, and maintenance training. Hot flash incidence declined for all 6 patients from 59% to 100% (mean 73%) during the 12-week training
period and was sustained for 6 months following the training (Wijma et al, 1997). Another trial randomized postmenopausal women to compare 3 types of training: paced respiration, muscle relaxation, and alpha-wave electroencephalographic biofeedback and found that paced respiration was most effective in reducing hot flashes (Freeman & Woodward, 1992). A 5 week relaxation response training significantly increased reaction time on a simple attention/psychomotor task on healthy ageing adults (Galvin et al, 2006). A Swedish study declared that both cognitive behavior therapy & Kundalini yoga to be promising stress management techniques as significant improvement is observed in psychological (self-rated stress and stress behavior, anger, exhaustion, quality of life) and physiological (blood pressure, heart rate, urinary catecholamines, salivary cortisol) measurements in both (Granath et al, 2006). Meditation has been described as training in awareness, which when kept over long periods produces definite changes in perception, attention and cognition (Brown, 1977). It has also been shown that processing of sensory information at the thalamic level is facilitated during the practice of pranayama (Telles et al, 1992) and mediation (Telles & Desiraju, 1993) these two practices, along with physical postures (asanas), theory and philosophy of yoga were found to improve hand steadiness in college students following 10 days of practice. Another study observed significant improvement in visual perception in college students after 10 days of yoga training (Telles et al, 1993). This improvement is believed to be due to improved eye hand coordination, attention, concentration, and relaxation, as well (Telles et al, 1995).

With these promising benefits of yoga, we could hypothesize that yoga may decrease the clinical symptoms of climacteric, cognitive dysfunction and psychological symptoms in perimenopausal women. There are very few studies on
yoga or meditation using relaxation therapies to see a change in climacteric symptoms. The present study was designed to explore the factor structure of the 11 item Menopause rating scale and 21 item Greene Climacteric Scale in Indian women and also to examine the efficacy of integrated approach of yoga therapy (IAYT), a non-pharmacological therapy, which offers techniques to promote positive health at physical, mental, social and spiritual level.

2. REVIEW OF LITERATURE

2.1 From the Ayurveda texts

2.2 From Scientific research studies

2.2.1 Cross cultural studies on perception and traditional treatments adopted for climacteric syndrome

2.2.2 Studies on relaxation techniques and climacteric syndrome

2.2.3 Studies on relaxation techniques which can be applied in climacteric syndrome

2.2.4 Studies on physical exercise and climacteric syndrome

2.2.5 Studies on hormone replacement therapy

2.2.6 Studies on complementary and alternative therapies