

*AVM*

**EFFECT OF INTEGRATED APPROACH OF YOGA THERAPY ON THE  
VASOMOTOR, COGNITIVE AND PSYCHOLOGICAL SYMPTOMS ON  
CLIMACTERIC SYNDROME**

*Thesis submitted by*

Ritu Chattha



*Towards the partial fulfillment of*  
**DOCTOR OF PHILOSOPHY (YOGA)**

January 2008

Swami Vivekananda Yoga Anusandhana Samsthana  
(SVYASA)

(A University, Established under section 30 of the UGC Act, 1956 vide Notification

No. F.945/2001-03, Dated 8-4-2001 of the Government of India)

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CLIMACTERIC SYNDROME**

*Thesis Submitted for the Award of*  
**DOCTOR OF PHILOSOPHY (YOGA)**

By  
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(A University, Established under section 30 of the UGC Act, 1956 vide Notification  
No. F.945/2001-03, Dated 8-4-2001 of the Government of India)

## **DECLARATION**

I, hereby declare that this study was conducted by me at Swami Vivekananda Yoga Anusandhana Samsthana (SVYASA), Bangalore, under the guidance of Dr. Nagarathna Raghuram, Dean of Life science and Dr. Padmalatha Venkatram, an obstetrician & gynecologist and Dr. H.R. Nagendra, Vice Chancellor, Swami Vivekananda Yoga Anusandhana Samsthana, Deemed University, Bangalore.

I also declare that the subject matter of my thesis entitled EFFECT OF INTEGRATED APPROACH OF YOGA THERAPY ON THE VASOMOTOR, COGNITIVE AND PSYCHOLOGICAL SYMPTOMS ON CLIMACTERIC SYNDROME has not previously formed the basis of the award of any degree, diploma, associate-ship, fellowship or similar titles.

Date:

Place: Bangalore

**RITU CHATTA**

(Candidate)

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My humble offerings to the unseen faculty, the supreme power who has made me worthy of this effort, keeping me blessed with all chosen, intellectual people.

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**STANDARD INTERNATIONAL TRANSLITERATION CODE USED TO  
TRANSLITERATE SANSKRIT WORDS**

a	=	अ	na	=	न	pa	=	प
ā	=	आ	ca	=	च	pha	=	फ
i	=	इ	cha	=	छ	ba	=	ब
ī	=	ई	ja	=	ज	bha	=	भ
u	=	उ	jha	=	झ	ma	=	म
ū	=	ऊ	ñ	=	ञ	ya	=	य
e	=	ए	ṭa	=	ट	ra	=	र
ai	=	ऐ	ṭha	=	ठ	la	=	ल
o	=	ओ	ḍa	=	ड	va	=	व
au	=	औ	ḍha	=	ढ	sa	=	स
m	=	अं	ṇa	=	ण	śa	=	श
ḥ	=	अः	ta	=	त	ṣa	=	ष
ka	=	क	tha	=	थ	ha	=	ह
kha	=	ख	da	=	द	kṣa	=	क्ष
ga	=	ग	dha	=	घ	tra	=	त्र
gha	=	घ	na	=	न	jña	=	ज्ञ

## ABSTRACT

Background

STUDY - 1

The standardized menopause-specific instruments which measure symptoms of the climacteric need to have sound psychometric properties and must demonstrate construct validity for different populations of women. The elucidation of the internal structure of the Menopause Rating Scale (MRS) through factor analysis has been largely for western populations so far. The only study for an Asian population seems to be a study for women in Indonesia. This paper presents a factor analysis of the MRS for menopausal women in India.

The development of the Greene Climacteric Scale (GCS), a scale of 21 items, was motivated by the examination of seven separate studies in which the number of items on the scale to assess the climacteric varied considerably (from 17 to 36). Greene initially conducted a factor analysis on a list of 30 symptoms reported by women aged 40-55 using a 30 item questionnaire in the United Kingdom. He identified three symptom clusters and labeled them as vasomotor, somatic and psychological. This was followed by an analysis on an Indian population by Indira and Murthy who also used the same 30 item questionnaire and found eight factors. Other studies found between four and seven factors. The composite scale of Greene's 21 items is the one that is studied in this paper. The goal of this paper is to explore the factor structure of the 21 item Greene Climacteric Scale in Indian women.

## **STUDY - 2**

Climacteric is a physiologic transition characterized by depletion of the ovarian follicles, loss of the menstrual cycle, decreased estradiol production and typical symptoms. The ovarian failure could influence the mental neurotransmission of menopausal women; female menopausal brain could suffer of a negative homeostasis in the absence of estrogen, affecting the cognition and daily behavior. The biologic and psychosocial events accompanying menopause which can be classified as

stressors and "facilitators", and for the predisposed women, are likely to cause psychiatric disorders. Hormone replacement therapy (HRT) no doubt reverts the cognitive, vasomotor, psychological and autonomic impairments but also holds a risk of breast cancer, 3-fold risk of venous thromboembolism and inducing feelings of fear. HRT could not bring any change in coping strategies in healthy postmenopausal women as the stress coping is an individual propensity and not dependant on specific hormonal status during menopause. Due to the serious adverse effects of HRT, 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. Yoga aims at relaxation and mental awareness is known to alter the perceptions, and mental responses to both external and internal stimuli, slow down reactivity and responses to stressful stimuli. Several studies on applied relaxation, relaxation response showed reduction in hot flushes intensity, anxiety and depression in menopausal women. Hence, the present hypothesis expects that yoga may decrease the clinical symptoms of climacteric, cognitive dysfunction and psychological symptoms in perimenopausal women.

## **Aims**

### **STUDY – 1**

The study aimed to do a factor analysis of Menopause Rating Scale and the Greene Climacteric Scale for a population of Indian perimenopausal women.

### **STUDY – 2**

This study aimed at assessing the vasomotor, cognitive and psychological functions in 108 perimenopausal women between 40-55 years after eight weeks of integrated approach of yoga therapy (IAYT).

## **Methods**

### **STUDY – 1**

A sample of 518 perimenopausal women aged between 45 and 55 were asked to fill in the Menopause Rating Scale and Greene Climacteric Scale.

### **STUDY - 2**

This was a prospective randomized controlled trial wherein 108 participants (married or single) who satisfied the inclusion criteria of (a) age between 40 to 55 years, (b) serum follicle stimulating hormone (FSH) level equal to or higher than 15mIU/ml (by Electro chemiluminescence method using Roche Elecsys 2010 FSH kit) were randomly divided equally into two groups; one group practiced integrated approach of yoga therapy (IAYT) and the other practiced a set of physical exercises. Participants were recruited from gynecological outpatient clinics in different areas of Bangalore. Participants were assessed for the cognitive tests through Six-Letter Cancellation Test (SLCT), Punit Govil Intelligence Memory Scale (PGIMS), psychological assessments through Eysenck's Personality Inventory (EPI), Perceived Stress Scale (PSS) and vasomotor scale symptom checklists through Menopause Rating Scale (MRS) and Greene Climacteric Scale (GCS) before and after the 8 weeks of intervention. Both experimental and control groups practiced IAYT and physical exercise respectively for one hour per day, 5 days per week for 8 weeks.

## **Results and Discussion:**

### **STUDY – 1**

The mean age of the women was  $48.03 \pm 3.40$ . For MRS, three factors, psychological, urogenital and somatic were extracted. The item on sleep problems reported by previous factor analyses to be part of the somatic group was found to be part of the psychological group in this study. The rest of the groupings agree with studies on other populations. The urogenital symptoms account for a slightly larger amount of variance compared to the somatic group, in contrast to previous studies. The mean and standard deviations of the three subscales are as follows: Psychological:  $5.59 \pm 4.14$ , Urogenital:  $1.78 \pm 2.1$ , Somatic:  $2.96 \pm 2.30$ .

The factor analysis of the GCS data using an oblique rotation yielded three distinct factors with loadings more than 0.4. The breakup of the psychological factor into an anxiety and a depression factor which has been hypothesized earlier could only be verified using varimax rotation. The last item, “Loss of sexual interest” is shown to be part of the vasomotor factor. The means of the scores on the three factors are: Psychological:  $8.28 \pm 5.87$ , Somatic:  $4.64 \pm 3.73$ , Vasomotor:  $2.39 \pm 2.10$ . These are much lower than the values given by Greene, but are in consonance with values published in two earlier studies for different populations.

## **STUDY – 2**

There was a significant difference ( $p < 0.05$ ) between groups in the vasomotor factor, a marginally significant difference ( $p = 0.06$ ) in psychological and no change in somatic component. Within group analysis showed significant improvement in all three factors in yoga group ( $p < 0.001$ ) and in only psychological factor ( $p < 0.05$ ) in control group. There was a highly significant ( $p < 0.001$ ) difference in SLCT and 8/10 sub-tests of PGIMS (remote memory, mental balance, attention concentration, delayed recall, immediate recall, verbal retention (ii), visual retention and recognition test) between

the two groups. The effect sizes were higher in yoga group in SLCT and 7 subtests of PGIMS except one (verbal retention of dissimilar pairs) where the control group had higher effect size. There was a highly significant difference between the groups in perceived stress level ( $p < 0.001$ ) and significant change in extroversion and neuroticism scores ( $p < 0.05$ ) between the two groups. Also, stress and neurotic behavior showed highly significant ( $p < 0.001$ ) change within yoga group whereas stress levels alone show a significant change ( $p < 0.05$ ) in the control group after the 8 weeks intervention.

***Conclusions:***

The MRS scores compared with an Indonesian population shows that the latter have lower scores and that the scores in this study are comparable to the scores for Latin Americans. The factor analysis on GCS study reports the prevalence of symptoms in Indian perimenopausal women and constructed symptom groupings from reported symptoms. The findings of this factor analysis may be used as normative data for future studies.

Integrated approach of yoga therapy can improve vasomotor symptoms and the cognitive functions in perimenopausal women. It helps them to recognize the stressors in their lives, calm down, alleviate the stress and cope with their physiological and psychological symptoms of menopause better than those who practiced physical exercises.

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## 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)

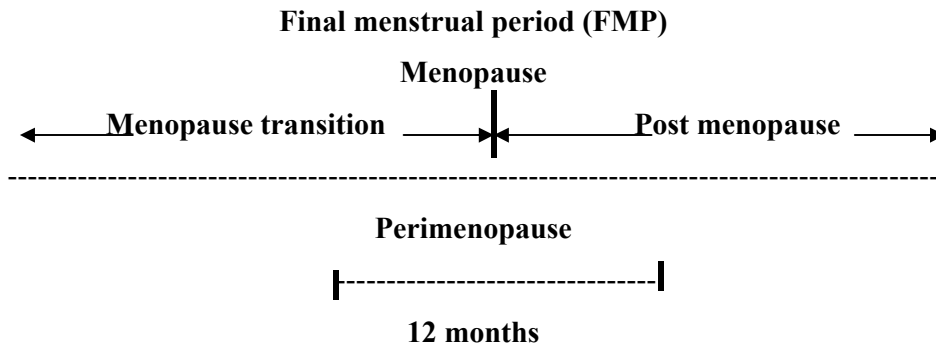
Ten percent cease abruptly. The perimenopausal transition and mean circulating hormone levels (Gordon & Speroff, 2002).

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



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).



**Changes in menstrual cycle at the approach of the menopause:**

Age group length (years)	Follicular phase (days)	Luteal phase (days)	Total cycle (days)
18 – 30	16.9 ± 3.7	12.9 ± 1.8	30.0 ± 3.6
40 – 41	10.4 ± 2.9	15.0 ± 0.9	25.4 ± 2.3
46 – 50	8.6 ± 2.8	15.9 ± 1.3	23.2 ± 2.9

(Treolar et al,

1967)

**Changes in circulating hormone levels at menopause**

	Premenopause	
<b>Postmenopause</b>		
Estradiol	40 to 4000 pg/ml	10 to 20 pg/ml
Estrone	30 to 200 pg/ml	30 to 70 pg/ml

Testosterone	20 to 80 ng/dl	15 to 70 ng/dl
Androstenedione	60 to 300 ng/dl	30 to 150 ng/dl
Follicle stimulating hormone	2.9 to 12.5 mIU/ml	23 to 116.3 mIU/ml

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(Gordon & Speroff,  
2002)

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 20fold 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

index (Stewart et al, 1992). 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  $17\beta$  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**

## 2.1 From the *Ayurveda* texts

### रजोनिवृत्ति (आयुर्वेद)

(Menopause in Ayurveda)

Meaning of 'Ayus' as suggested by *Mahārṣi Punarvāsu*:

शरीरेन्द्रियसत्त्वात्म सन्योगो धारि जेवितम्

नित्यगश्चानुबन्धश्च पर्यायैरायुररुच्यते ॥

*śarīrendriyasatvātma sanyogo dhāri jeevitam*

*nityagaścānubandhaśca paryāyairāyurarucyate ॥*

सुश्रुत संहिता शरीर स्थान १।४२।

suśruta saṁhitā śarīra sthāna 1 / 42

'Ayus', the life represents a combination of the body, the sense organs, the mind and the soul. The body made of the five *mahābhūtās* (basic elements) serves as an abode of the enjoyments and sufferings of the soul. The sense organs are the eyes; the sattva is the mind and the soul is the bearer of the knowledge (Bhishagrātna, 1991).

Sense organs, soul and body – these three are like a tripod, the world is sustained by their combination; they constitute the substratum for everything. This combination of the above three is *Purūṣa*; this is the subject matter of *Veda (Ayurveda)*; it is for this that this *Veda* is brought to light.

*Ayurveda* is the science, which deals in complete healthcare system having a traditional system of medicine. *Aṣṭāṅg Ayurveda* deals with eight branches of *Ayurvedic* treatment and in that *Prasūti tantra* i.e. the obstetrics and gynecology section form one of the main branch. *Ayurveda* describes various epochs of woman's life in a scattered manner presenting a general picture.

The life span is divided into three stages –

1. बालावस्था Bālāvasthā (childhood)
2. मध्यमावस्था Madhyamāvasthā (middle age)
3. वृद्धावस्था Vrddhāvasthā (old age)

Talking about the divisions of age in woman's life,

1. बाल्यावस्था Balawastha:

- (a) बाला Bālā– 10 years
- (b) कुमारी Kumārī– 10 -12 years
- (c) रजोमती Rajomatī - 12-16 years, beginning with the onset of menarche.

2. मध्यमावस्था Madhayamawastha:

- (a) युवती Yuwati – 16 - 40 years
- (b) प्रौढा Prauḍhā– 40 - years
- (c) वृद्धा Vrddha - 50 years onwards

The term used for women after 50 years is “रजोनिवृत्ति Rajonivrtti”, this corresponds to menopause in Allopathy.

➤ Age of “रजोनिवृत्ति” Rajonivrtti:

जरापक्वशरीराणां याति पन्चाशतः क्षयम् ॥

*jarāpakvaśarīrāṇāṃ yāti pancāśata kṣayam //*

सुश्रुत संहिता शरीर स्थान ३ । ८

suśruta saṁhitā śarīra sthāna 3 / 8

योषितश्चोनद्वादशात्तीतपन्चाशद्वर्षाया रजस्तन्यादय इति ॥

*yoṣitaśconadvādaśāttītapancāśadvārṣāyā rajastanyādaya iti*

अष्टाङ्ग संग्रह शरीर स्थान १ । २१

aṣṭāṅga saṅgraha śarīra sthāna 1 / 21

वत्सराद् द्वादशादूर्ध्वं याति पन्चाशतः क्षयम् ॥

*vatsarād dvādaśādūrdhva yāti pancāśata kṣayam*

अष्टाङ्ग हृदय शरीर स्थान १ । ७

aṣṭāṅga hradaya śarīra sthāna 1 / 7

In women, the rajas (menstrual blood) which is the product of *rasā* (the first

*dhātu*), flow out of the body for three days, every months, after the age of

twelve years and undergoes diminution by age of fifty years.

Twelve and fifty years are the age of menarche and menopause respectively.

*Kāśyap* mentions the age as sixteen years, which is probably the description of

appropriate age for conception. He further says that this age can be influenced by specific *āhāra* (dietetics), and *ārogya* (health). *Arundatta* opines that these are probable ages. There may be slight variation in individual case as menarche may come at eleven years similarly age of menopause may also be delayed. *Suśruta* has enumerated amenorrhoea and oligomenorrhoea and pain in the vagina etc symptoms occurring due to loss of *ārtava*. *Cakrapāṇi* has explained that these symptoms are caused by *vāyu* aggravated due to loss of *ārtava* responsible for proper nourishment of reproductive system. This reference indicates that probably *ārtava* refers to estrogen (Tewari, 1977).

➤ **Status of doshas in “रजोनिवृत्ति” Rajonivrtti:**

अथातो योनिव्यापच्चिकित्सितं व्याख्यास्यामः ॥ १ ॥

athāto yonivyāpaccikitsitaṁ vyākhyāsyāmah

इति ह स्माह भगवानात्रेयः ॥ २ ॥

iti ha smāha bhagavānātreya

चरक संहिता चिकित्सा स्थान ३०। १। २

caraka saṁhitā cikitsā sthāna 30 / 1,2

Now we shall expound the chapter on the “Treatment of Gynaec disorders”.

Thus said Lord Atreyā.

*Yoni-vyāpat* (Gynaec morbidities) which is also caused by the aggravated *vāyu* in general is being described in this chapter. As it is said, “the genital organs of women do not get afflicted without the aggravated *vāyu*”

यच्च वातविकाराणां कर्मोक्तं तच्च कारयेत् ॥ ११४ ॥

सर्वव्यापत्सु मतिमान्महायोण्यां विशेषतः ।

*yacca vātavikārāṇām karmoktaṁ tacca kārayet // 114//  
sarvavyāpatsu matimān mahāyoniyām viśeṣata /*

चरक संहिता चिकित्सा स्थान ३० । ११४  
caraka saṁhitā cikitsā sthāna 30 / 114

In all types of gynaec disorders, and specially in *mahāyoni* variety, a wise physician should administer all the therapeutic measures prescribed for the treatment of diseases caused by *vāyu*.

न हि वातादृते योनिर्नारीणां संप्रदुष्यति ॥ ११५ ॥  
शमयित्वा तमन्यस्य कुर्याद्दोषस्य भेषजम् ।

*na hi vātādrate yonirnārīṇām sampraduṣyati // 115//  
śamayitvā tamanyasya kuryāddoṣasya bheṣajam /*

चरक संहिता चिकित्सा स्थान ३० । ११५  
caraka saṁhitā cikitsā sthāna 30 / 115

A woman never suffers from gynecic diseases except as a result of affliction by aggravated *vāyu*. Therefore, first of all, the aggravated *vāyu* should be alleviated, and only thereafter, therapies should be administered for the alleviation of other doṣās.

➤ **Concepts of Menopause from contemporary texts on Ayurveda:**

Ayurveda experts define “रजोनिवृत्ति Rajonivrtti” Menopausal Syndrome as a group of symptoms produced by degenerative changes after completion of adult age & the start of geriatric.

Menopause is a natural transition, which every woman experiences in her life. It is the ending of a woman's monthly menstrual periods and ovulation. It also signals other changes to the body and mind, brought on in part because the body begins

producing lesser amounts of the hormones estrogen and progesterone (among others). Menopause is not a disease. It is a natural process in a woman's life. Menopause is a natural hormone (estrogen) deficient state that occurs at the age of 45-55 years. Ayurveda associates menopause with aging. Aging is a 'Vāta' predominant stage of life. Thus, the symptoms of menopause experienced by some women are similar to the symptoms seen when the Vāta doṣa rises and upsets the normal balance of the body.

➤ **Vāta Characteristics**

रूक्षः शीतो लघुः सूक्ष्मश्चलोऽथ विशदः खरः ।

विपरीतगुणैर्द्रव्यैर्मारूतः संप्रशाम्यति ॥

*rūkṣah śīto laghuhu sūkṣmaścalo tha viśadaha kharaha ।*

*vīparītaguṇairdravyairmārūta sampraśāmyati //*

चरक संहिता सूत्रस्थान ७।५९।

caraka saṁhitā cikitsā sthāna 7 /59/

Vāta, which is rough, cool, light, subtle, mobile, non-slimy and coarse, is reconciled by medicines having opposite qualities (Sharma & Bhagwan, 2005).

**Tridhātu in Rikveda:**

त्रिधातु शर्म वाहतं शुभस्पतौ ॥ रिक् सं १।३।६।

*tridhātu śarma vāhataṁ śubhaspatau // rik saṁhitā 1 /3 /6 /*

A reference to these three physiological factors of Vāyu, Pittam and Kapham, under the name of Tridhātu, is first met with in the Rikveda.

*Suśruta* as a surgeon derived the root “*Vā*”, to move, to spread. *Vāyu*, according to *Suśruta*, is so called from the fact of its sensory and motor functions such as, smelling etc. But the *Vāyu* in the Ayurveda is not wholly a physical or organic force.

In *Mahābhārata*, *Prāṇa vāyu* is described as a force, akin to electricity. It is somewhat like a flash of lightening. This fact at once shows the errors of confounding *Prāṇa vāyu* with an effete material with gases generated during the processes of digestion. *Suśruta* describes it as force, which sets the whole organism into motion.

*Suśruta* attempts classification of *Vāyu* into *Prāṇa*, *Apāna*, *Samāna*, *Udāna*, *Vyāna* which in detail, correspond to the divisions of functions performed by the Cerebro spinal and Sympathetic nerves of the Western physiology. In short, the term *Vāyu* may be understood as a kind of electro-motor or molecular force (as when we speak of the *Vāyu* of the soil), though the term is loosely applied now to signify as mere gas or air.

➤ ***Upaniṣadic concept of Ayu, Vāyu and Prāna:***

Our sacred Upanishads tell us in the first place, आयु प्राणः “*Ayu Prāṇa*” are one and the same principle.

यः प्राणः स वायुः

yah prāṇah sah vāyuh

In the second place, *Prāṇa* and *Ayu* are identical. In the third place, *Vāyu* is not unlike ether.

वायुर्वाव संवर्गः वायुरिव देवेषु प्राणः प्राणेषु ॥

*vāyurvāva samvarga vāyuriva deveṣu prāṇa prāṇeṣu //*

*Vāyu* is the universal store of energy; in the physical world, it is known by the name of *Vāyu*; in the living world it is called under a different name and that name is *Prāṇa*.

*Prāṇa* force is acting on an aggregated living body, divides itself into five distinct forces, *Prāṇa*, *Apāna*, *Samāna*, *Udāna*, *Vyāna* and subserves the functions of correlation and sustentation and controls oxidation.

➤ **Sushruta quotes in his commentary on Vedānta darśana:**

The five divisions of *Vāyu* on its living aggregate:

Life gets knotted into five divisions, *Prāṇa*, *Apāna*, *Samāna*, *Udāna*, *Vyāna* and this acting on any aggregate living matter is called *Prāṇa*. So, what we call *Prāṇa* is not the *Vāyu* itself, but a particular mode of its motion (Bhishagrata, 1991).

➤ **वातवृद्धि लक्षणम् *Vāta Vrddhi Lakshanam:***

कुपितस्तु खलु शरीरे शरीरं नानाविधैर्विकारैरूपतपति बलवर्णसुखायुषामुपघातय मनो व्याहर्षयति:

सर्वोन्द्रियाष्युवहन्ति विनिहन्ति गर्भान विकृतिमापादयत्यतिकालं वा धारयति

भयशोकमोहदैन्यातिप्रलापाञ्जनयति प्राणांश्चोपरुणद्दि ॥

*kupitastu khalu śarīre śarīraṁ nānāvidhairvikārairūpatapati*

*balavarṇasukhāyuṣāmupaghātayaḥ mano byāharṣayatiḥ*

*sarvondriyāṣyuvahanti vinihanti garbhāna vikṛtimāpādayatyatikālaṁ vā dhārayati*

*bhayaśokamohadainyatipralāpāñjanayati*

*prāṇānāyoparuṇaddi ॥*

Vitiated *vāta* produces many diseases, affects strength, colour, happiness, lifespan. Doesn't allow mind to feel happiness, affects all sense organs & organs of actions causes the improper growth of the fetus. Produces fear, sorrowness, delusion, miserable condition, irrelevant talking and destroys *Prāṇas* also.

काश्यकाष्ण्यगात्रकम्पस्फुरणोष्णकातसंजनानिद्रानाश  
बलेन्द्रियोपघाताथिशूलज्जाशोषमलसगाध्मानाटोपमोह  
दैन्यभयशोकप्रलापादिभिवृद्धो वायु पीडयति  
*kāśyākārṣṇyagātrakampasphuraṇoṣṇakātasaṁjnānidrānāśa*  
*balendriyopaghātāthiśūlajjāśoṣamalasagādhmānāṭopamoha*  
*dainyabhayaśokapralāpādibhirvūdhdo vāyu pīdayati*

अष्टाङ्ग संग्रह सूत्रस्थान स्थान १९। ५।

aṣṭāṅga saṅgraha sūtrasthāna 19 / 5

Vitiated (increased) *vāta* causes emaciation of the body, blackness, tremors in the body, palpitation, desire for hot foods and environment, loss of sleep, consciousness, affects strength and sense organs as well as organs of action. And it also causes pain, dryness of bone marrow, constipation, and flatulence, distention of abdomen, delusion, miserable condition, fear, sorrow, irrelevant talks.

वृद्धस्तु कुरते निलः काश्यकाष्ण्योष्णकामत्व कमपानाहशक्रद्ब्रह्मान्  
बलनिद्रेन्द्रियभ्रंशप्रलाप भ्रमदीनता ॥  
*vradhdastu kurate nila kāśyākārṣṇyoṣṇakāmatva kamapānāhaśakradbrahān*  
*balanidrendriyabhraṁśapralāpa bhramadīnatā //*

अष्टाङ्ग हृदय सूत्रस्थान ११। ५। ६।

aṣṭāṅga hradaya sūtrasthāna 11/ 5, 6

Vitiated (increased) *vāta* causes emaciation, blackness, desire for hot food and environment, tremors, flatulence, constipation, affects strength, sleep sense organs and organs of action. It also causes irrelevant talk, wandering tendency, miserable condition.

तत्र वातवृद्धौ वाकपारूष्य कार्श्यं काष्ण्यं

गात्रस्फुरणयुष्णकायिता निद्रानाशोऽल्पबलत्वं गाढवर्चस्त्वं च ।।

*tatra vātavraddhau vākparūṣya kārśya kārṣṇya*

*gātrasphuraṇayuşṇakāyitā nidrānāśo lpabalatvaṁ gāḍha varcastvaṁ ca //*

सुश्रुत संहिता सूत्रस्थान १५ । १८

suśruta saṁhitā sūtrasthāna 15/18

Vitiated (increased) *vāta* causes hoarse voice, emaciation, blackness, palpitation, desire for hot food and environment, loss of sleep, reduced strength.

### ➤ Symptoms of Vāta Aggravation

Worried

Tired, yet can't relax, Fatigue, poor stamina

Nervous, Can't concentrate

Anxious, fearful

Agitated mind

Impatient, Antsy or hyperactive

Spaced out

Self-defeating

Shy, insecure, Restless

Cannot make decisions

Weight loss, under weight

Insomnia; wake up at night and can't go back to sleep

Generalized aches, sharp pains, Arthritis, stiff and painful joints

Agitated movement

Very sensitive to cold

Nail biting

Rough, flaky skin, Chapped lips

Fainting spells

Heart palpitations

Constipation, Intestinal bloating, gas, Belching, hiccups

Dry, sore throat, Dry eyes

➤ **Ayurveda recommendations:**

“*Rasayana Chikitsa*” rejuvenation therapy, a specialized branch to check the degenerative process of the bodily tissues is found to be very useful as per reference given by *Charaka*. (Ch.S.Chi 1-1/7,8). *Ayurveda* recommends *Dashmool*, Naturocal capsule, *Medha* capsule, *Shatawari* etc. in this condition. The effect of *Shirodhara* with *Ksheerbala* tail with *Jyotishmati* tail shows remarkable results in this condition (Sushma, 2007).

## **2.2 From Scientific research studies**

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

Bharadwaj (1983) interviewed 495 women who had reached natural menopause, 370 of them attended medical out patient department of the K.E.M. Hospital for minor complaints. They belonged to the lower socioeconomic group (Group I). One 125 belonging to higher socio-economic group (Group II) were friends and relations of the investigators. He found the difference between the two groups regarding the age at menarche and the reproductive period was statistically not significant. The two groups differed significantly in the prevalence of menopausal symptoms, particularly with reference to headache and irritability. The difference in the prevalence of menopausal symptoms between the two groups was probably attributed to the tendency of the lower socio-economic group of women to ignore the symptoms as compared to the higher socio-economic group.

Sengupta (2003) stated in his paper that a total of 130 million Indian women are expected to live beyond the menopause into old age by 2015. The menopause is emerging as an issue owing to rapid globalization, urbanization, awareness and increased longevity in urban middle-aged Indian women, who are evolving as a homogeneous group. Improved economic conditions and education may cause the attitude of rural workingwomen to be more positive towards the menopause.

However, most remain oblivious of the short- and long-term implications of the morbid conditions associated with middle and old age, simply because of lack of awareness, and the unavailability or ever-increasing cost of the medical and social support systems.

Singh & Arora (2005) ascertained the profile of menopausal women in rural north India. Six villages were selected in a rural field practice area of Department of Community Medicine, Postgraduate Institute of Medical Education and Research, Chandigarh, north India. Data was obtained during 1999–2001 by interviewing women aged 35–55 years. Of the 558 enlisted women, 152 (27.2%) had attained menopause. Average age at menopause was 44.1 years. More than half (53%) reported seven or more symptoms at menopause. Diminished vision was reported as the most common symptom at menopause. The majority (85%) admitted that menopause adversely affected women's physical health. However, most of them (95%) considered menopause socially good for women and welcomed it. None of our respondents reported use of hormone replacement therapy.

Kaur (2004) ascertained the effect of menopause on the lives of women in suburban Chandigarh. An integrated qualitative and quantitative study was performed in a low socioeconomic area of Chandigarh city, India. Women aged 40-60 years were enlisted and interviewed. Of the 725 enlisted women. The transition phase lasted for 1-12 months in 48.7% of cases and for 1 year or more in 20.8% of cases. No transitional changes were reported by 30.5% of women. The majority of women interviewed (76%) did not experience any tension on attainment of menopause. Hot flushes were reported by 17.1% of women. Most women (94%) welcomed menopause. Use of hormone replacement therapy was not reported by anyone.

Although north Indian women experienced various symptoms at menopause, they largely ignored these, while welcoming the freedom from menstruation-related worries.

Yahya (2003) studied the perceptions of Pakistani women regarding menopause. Study conducted in the suburb of Lahore from 1st July 2000 to 31st August 2000. The data were collected from a rural population of 28,419 individuals living in 20 villages outside Lahore. A systematic random sample of 130 women was drawn from those 1337 women, who had reached natural menopause. The age of the population ranged from 42 to 80 years with a mean of  $59.8 \pm 7.4$  years. The mean age at menopause was  $49.0 \pm 3.6$  years. Majority of the women (82.3%) considered menopause as a positive change. According to 71.6% women, their relationship with the family had either improved or there was no change. The proportion of women showing a positive attitude towards menopause was significantly higher among our study subjects as compared to those from India, Thailand, USA and Australia. The majority of study subjects did not consider menopause as a negative milestone, loss of time, a partial death or a disease as seen in many western populations.

Aaron et al (2002) studied the effect of menopause on women in rural south India. They conducted a population-based cross-sectional study on perceptions regarding menopause, prevalence of menopausal symptoms and association of family environmental factors with menopausal symptoms among 100 postmenopausal and 100 premenopausal rural women. 57% of postmenopausal women perceived menopause as convenient. 69% of them complained of diminishing abilities after menopause. 23% felt that sexual life ends with the onset of menopause. 16% reported that their husbands had become disinterested in them after menopause and 11% were apprehensive about the loss of femininity. A higher proportion of postmenopausal

women reported hot flushes, night sweats, urge incontinence and other somatic symptoms as compared to premenopausal women. There was no significant association between menopause and depression. A poor perceived relationship within the family was shown to have a significant association with depression. There was a significant association between multiple somatic symptoms and menopause. A significantly higher proportion of postmenopausal women suffer from vasomotor symptoms, urge incontinence, loss of sexual desire and multiple somatic symptoms. They do not link these symptoms with menopause. Poor family environmental factors have a stronger association with depression than menopause.

George (1996) conducted a study of the experience of menopause among middle-aged women in a fishing village on the southwest coast of India. These women lived in a harsh environment with a standard of living that would be considered economically deprived by an outsider. The women had established their identity as fish sellers. Although they reported experiencing some of the physiological symptoms of menopause typically reported in Western literature, the symptoms were not cause for complaint, and none of them sought medical treatment for them. Nor did these women go through an identity crisis at midlife; they continued to identify themselves as well-established fish sellers, not as redundant, aging housewives. Furthermore, menopause gave them much more time and freedom to pursue their fish-selling business.

It opens with a brief review of the literature: the historical perspectives of menopause as an affliction, the modern perspective of menopause as a deficiency disease corrected with estrogen supplements, and the conflicted and limited nature of data on women's experience of menopause in developing countries

Data were gathered in 1995 on 190 women 35-69 years old. The most frequently reported symptom of menopause, after menstrual irregularity, was weight gain. Only 26% of the women had experienced hot flashes, but none thought they were severe. Vaginal dryness was reported by 18%. The women believed menopause to be natural and to be a positive development because it made it easier for them to go on their selling rounds without personal hygiene difficulties.

Boulet (1994) tried to answer the question: The menopause is universal, but what about the climacteric? In an attempt to answer this question, a study was conducted in seven south-east Asian countries, namely, Hong Kong, Indonesia, Korea, Malaysia, the Philippines, Singapore and Taiwan. 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 percentages of women who reported the more psychological types of complaint were similar to those in western countries. A physician was consulted for climacteric complaints by 20% of the respondents, although this was most frequently associated with the occurrence of psychological complaints and less so with that of hot flushes and sweating.

Ethnic background and age at menarche were found to have a significant influence on age at menopause. The study clearly demonstrated that climacteric complaints occur in south-east Asia. The findings suggest, however, that vasomotor-complaint-related distress might be 'translated' into psychological complaints, which are more frequently considered to warrant consulting a physician.

Kowalcek (2005) studied the cross-cultural and intra-cultural differences between the perception and the experience of menopause in pre-menopausal and post-menopausal German and Papua New Guineas women. Concepts concerning

menopause and the experience of the menopause were assessed by the symptom categories (i.e. hot flashes, cardiac or sleeping disorders, depression, irritability, lack of drive, vaginal dryness, painful joints or muscles) according to the Menopause Rating Scale (MRS). In addition to the translated English version, a questionnaire in Pidgin-English was offered. Questions about positive and negative expectations of menopause and the acceptance of hormonal replacement therapy were included. 101 pre-menopausal and 40 post-menopausal women in Germany as well as 36 pre-menopausal and 41 post-menopausal women in Papua New Guinea were questioned. The expectations regarding the menopause differed significantly in favor of a higher trait intensity concerning the item of hot flashes in Germany and a significantly higher trait intensity in the items cardiac trouble, lack of drive, urological symptoms, vaginal dryness, joint and muscle symptoms in Papua New Guinea. In the menopause experience, significant differences between the cultures are confirmed in favor of a higher trait intensity in Papua New Guinea concerning experienced depression, drop in performance, sexual disturbances and vaginal dryness. The intra-cultural comparison between the concepts concerning menopause and the menopause experience in Germany shows a significantly higher trait intensity with regard to the expected disturbance from hot flashes, depression, agitation, lack of drive and sexual problems as compared to the experienced disturbances.

Ho SC (1999) reported the prevalence of symptoms in the Hong Kong Chinese perimenopausal women. Compared with pre- and post-menopausal women, perimenopausal women had the highest reports of symptom complaints. Musculoskeletal complaints were the most prevalent complaints, followed by psychological symptoms.

Mikhail & Ragheb (1996) conducted a descriptive study to assess the health-related concerns and experiences of a sample of employed perimenopausal women in Alexandria, Egypt. In addition, they explored their **help-seeking behavior** and their perception of symptoms. Two hundred working women ages 40-60 years were interviewed, using a semistructured interview form as well as Koos's list of symptoms. The commonly mentioned concerns, in order of frequency, were chronic headaches, chronic fatigue, transportation and phone communication problems, financial problems, job dissatisfaction, backaches, hypertension, kidney disease and gall bladder disease, gastritis/indigestion, menstrual disturbances, arthritis, AIDS, and hepatitis B. With respect to the problems experienced by the women in the past 6 months, there was a high self-reported prevalence of headaches, fatigue, transportation and communication problems, backaches, job dissatisfaction, dissatisfaction with health insurance, financial problems, menstrual disturbances, gastritis/indigestion, gall bladder disease, anxiety, disturbed sleep, and hypertension. Women attempted to manage their problems mainly by taking over-the-counter drugs and self-prescribing (75.5%), doing nothing or using traditional remedies (56.5%), and going to a doctor or health insurance office (40%). Symptoms perceived by the majority of the women as not needing medical attention included loss of appetite, persistent backache, bleeding gums, chronic fatigue, persistent headaches, and loss of weight.

Tsao (2002) reported that although studies show that women view perimenopause as a natural process, few studies explore the experiences of Taiwanese mid-life women who visit clinics for perimenopausal health problems. Research is required to understand the patterns and explanations for the women's behaviours in the process of seeking medical help. Such understanding will help guide teaching and

care-giving approaches. The aim of this study was to generate a descriptive theoretical framework about the experiences of women who visited traditional Chinese and Western medicine clinics in Taiwan to seek medical help for perimenopausal symptoms. A grounded theory research design was used. Thirty Taiwanese women, aged 48-55 years, participated in two face-to-face audio-taped interviews. Trained staff nurses conducted the interviews. Data collection, coding of interviews and field notes, and data analysis occurred simultaneously. 'Relieving the discomforts' was the core theme for describing and guiding the process of seeking medical help during the perimenopausal period. During the process, 'Feeling the discomforts' was identified as the antecedent condition. Analyses showed five dimensions to the women's help-seeking behaviors: (1) searching for medical help, (2) taking medicine, (3) reassurance of health, (4) desiring to be understood, and (5) emotional swings. Women in this study expected to relieve their perimenopausal discomforts by finding treatment to match their body constitution. They hoped to find a caring and understanding doctor or staff member who would carefully explain health-related issues to them. Health care providers need to consider women's individual health values and, based on these values, use different approaches to treat and teach women with perimenopausal symptoms and concerns.

Tsao (2004) conducted quasi-experimental research which purpose to assess the effectiveness of a perimenopausal health education intervention for mid-life women in northern Taiwan. The health education intervention included a health education brochure, one-on-one teaching. 179 women were in the intervention group and 174 women were in the control group. Education effectiveness was assessed by participants' scores on four questionnaires at the beginning of the study and 3 months after initial recruitment. Both groups of women were compared on changes in their

scores on health knowledge, level of perceived uncertainty, health behaviors and perceived perimenopausal disturbances. The intervention group had significantly reduced scores on perimenopausal disturbances and reported increase practice of healthy behaviors compared to the control group. However, a significant decrease of perceived uncertainty was only found in the subgroup of women recruited from the Chinese medicine clinic of the control group. Chinese medicine physicians assess patients based on a philosophical approach that treats all symptoms holistically. This may have helped reduce patient uncertainty.

### **2.2.1 Summary**

- The prevalence of menopausal symptoms between low and high socio economic group differs probably due to the ignorance of symptoms in the lower socio-economic group of as compared to the higher socio-economic group.
- Evidence-based medicine is accessible to still only a few Indian women. Most menopausal women go untreated or use unproven alternative therapies.
- The majority of the women (85%) admitted that menopause adversely affected women's physical health. Most of them (95%) considered menopause socially good for women and welcomed it. None of our respondents reported use of hormone replacement therapy.
- Even in places like Lahore, the majority of study subjects did not consider menopause as a negative milestone, loss of time, a partial death or a disease as seen in many western populations.
- In the rural south India, there was a significant association between multiple somatic symptoms and menopause. A significantly higher proportion of postmenopausal women suffer from vasomotor symptoms, urge incontinence, loss

of sexual desire and multiple somatic symptoms. They do not link these symptoms with menopause.

- South Indian fisher women opine that menopause gave them much more time and freedom to pursue their fish-selling business.
- The climacteric experienced in south-east Asian countries was in a mild form. The prevalence of hot flushes and of sweating was lower than in western countries, but was nevertheless not negligible.
- A significant decrease of perceived uncertainty was only found in the subgroup of women recruited from the Chinese medicine clinic of the control group. Chinese medicine physicians assess patients based on a philosophical approach that treats all symptoms holistically.
- While vasomotor symptoms were significantly associated with menopausal status, their prevalence was comparatively lower than that reported in Caucasian populations.

### **2.2.2 Studies on relaxation techniques and climacteric syndrome**

In 1996 (Irvin et al), a randomized, controlled, prospective study investigated the efficacy of the elicitation of the relaxation response for the treatment of **menopausal hot flashes** and concurrent psychological symptoms. The volunteer sample consisted of 33 women, between the ages 44-66 years, in general good health, with a minimum of 6 months without a menstrual period, experiencing at least five hot flashes per 24-h, and not using hormone replacement therapy. The interventions used were relaxation response training and an attention-control group and a daily symptom diary measuring both the frequency and intensity of hot flashes, the Spielberger State-Trait Anxiety Inventory (STAI), and the Profile of Mood Scale (POMS) were the measures used. Subjects were randomly assigned to one of three groups (relaxation response, reading, or control) for the 10-week study. The relaxation response group demonstrated significant reductions in hot flash intensity, tension-anxiety and depression. The reading group demonstrated significant reductions in trait-anxiety and confusion-bewilderment. There were no significant changes for the control group.

Then in 1997, Wijma et al. tested applied relaxation (AR) in a series of six women with **postmenopausal hot flushes**. The AR program consisted of group instructions 1 hour per week over 12 week duration. The number of flushes were registered from 1 month before to 6 months after training AR. Menopausal symptoms (Kupperman Index), psychological well-being (Symptom Checklist), and mood (MOOD Scale) were measured at various moments during the study. For the six

patients the number of flushes decreased from the baseline period to 6 months follow-up with 59, 61, 62, 67, 89 and 100% respectively, in mean 73%.

Nedstrand et al. (1998) investigated whether **menopausal women** with vasomotor symptoms had a lower stress-coping than menopausal women without symptoms and if stress-coping changed when vasomotor symptoms had been effectively treated with estrogens. 16 women with vasomotor symptoms (target group) were treated with oral 17 beta-estradiol, 2 mg/day during 3 months. A comparison group was formed comprising 17 women without vasomotor symptoms. The Kupperman Index was used to cover menopausal characteristics in all women at baseline as well as at the second visit after 3 months. Stress-coping was measured by means of the Stress Coping Inventory. Their responses to the Eysenck's Personality Inventory were also recorded at the second visit. Women in the target group had a significantly lower stress-coping than women in the comparison group at baseline as well as after 3 months. Stress-coping did not change after estrogen therapy, although the vasomotor symptoms had virtually disappeared. Stress-coping did not change after estrogen therapy, although the vasomotor symptoms had virtually disappeared. Women in the target group successfully treated for vasomotor symptoms, had a significantly higher neuroticism score compared to the comparison group.

Complementary therapies are becoming increasingly popular in cultures dominated by biomedicine. Modalities are often extracted from various healing systems and cultural contexts and integrated into health care, expanding the focus from treatment of disease to the promotion of health. The cultural aspects of biomedicine are presented and compared and contrasted with other healing systems. Three healing systems; traditional Chinese medicine, Yoga, with roots in Ayurvedic

medicine and Shamanic healing illustrate these fundamental differences in approaches to healing. (Engebretson, 2002)

Galvin et al. (2006) studied the **relaxation response (RR)**, a mind-body intervention that counteracts the harmful effects of stress on **aging adults** as they are vulnerable to the effects of a negative emotional state. Convinced with the previous studies, in which relaxation techniques have shown the non-pharmacological benefit of reducing stress and improving the memory of **healthy older adults**, this pilot study evaluated whether a RR training program would decrease anxiety levels, improve attention, declarative memory performance and/or decrease salivary cortisol levels in healthy older adults. Fifteen adults participated and were randomly assigned to RR training or control groups with mean age 71.3 years and mean education level 17.9 years. Reaction time on a simple attention/psychomotor task was significantly improved with RR training, whereas there was no significant improvement on complex tasks of attention, verbal, or visual declarative memory tests. Self-reported state anxiety levels showed a marginally significant reduction. All subjects' salivary cortisol levels were within low-normal range and did not significantly change. This 5-week program in highly educated, mobile, healthy, aging adults significantly improved performance on a simple attention task.

Cohen et al. (2006) conducted a pilot trial in **14 postmenopausal** women experiencing  $\geq 4$  moderate to severe hot flushes per day or  $\geq 30$  moderate to severe hot flushes per week. This was to determine the feasibility and acceptability of a **restorative yoga** intervention for the treatment of hot flushes in postmenopausal women. The intervention consisted of 8 restorative yoga poses taught in a 3-h introductory session and 8 weekly 90-min sessions. Feasibility was measured by recruitment rates, subject retention and adherence. Acceptability was assessed by

subject interview and questionnaires. Efficacy measures included change in frequency and severity of hot flushes as recorded on a 7-day diary. Mean number of hot flushes per week decreased by 30.8% and mean hot flush score decreased 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.

### **2.2.2 Summary**

- The relaxation response group demonstrated significant reductions in hot flash intensity, tension-anxiety and depression.
- Applied relaxation introduced for six patients with hot flushes problem reduced (with mean 73%) the number of flushes from the baseline period to 6 months follow-up.
- Daily elicitation of the relaxation response leads to significant reductions in hot flash intensity and the concurrent psychological symptoms of tension-anxiety and depression. Stress-coping in women with moderate to severe vasomotor symptoms is unaffected by estrogens. Above studies indicate that a larger, randomized controlled trial to explore the efficacy of yoga for treatment of menopausal symptoms would be safe, feasible, cost effective and most importantly beneficial at this age.
- Ageing adults practiced relaxation response training which showed significant improvement in reaction time on a simple attention/psychomotor task whereas no significant improvement on complex tasks of attention, verbal, or visual declarative memory tests. Self-reported state anxiety levels showed a marginally significant reduction. All subjects' salivary cortisol levels were within low-normal range and did not significantly change.

- 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.

### **2.2.3 Studies on relaxation techniques which can be applied in menopausal syndrome**

Bera (1998) observed the recovery from induced physiological stress in *Shavasana* (a yogic relaxation posture) and two other postures (resting in chair and resting supine posture) was compared. Twenty one males and six females (age 21-30 yrs) were allowed to take rest in one of the above postures immediately after completing the scheduled treadmill running. The recovery was assessed in terms of Heart Rate (HR) and Blood pressure (BP). HR and BP were measured before and every two minutes after the treadmill running till they returned to the initial level. The results revealed that the effect of stress was reversed in significantly shorter time in *Shavasana*, compared to the resting posture in chair and a supine posture.

Bird & Wilson (1988) observed that there are increasing numbers of self-referral stress-management programs, a few of which use group-relaxation techniques, but few data are available on the personalities of the symptomatic and asymptomatic clients who attend or on any changes in personality after the program. Scores on the Eysenck's Personality Inventory, Multiple Health Locus of Control, and State-Trait Anxiety Inventory as well as demographic information were obtained from 255 adults who attended a 10-session, university-based, group-relaxation program. The symptomatic clients reported significantly less anxiety, less neuroticism, were more

extraverted and ascribed less of their behavior to chance at a 1 month post-treatment follow-up than at intake. The small group of asymptomatic clients also reported less anxiety and neuroticism at the follow-up. There were no sex differences on the Eysenck's inventory or the anxiety scales but there were for the Multiple Health internal and control scales. It was concluded that group relaxation appeared to improve mental health scores effectively for both stressed and nonstressed adults and that age was significantly related to some personality scores.

Vempati & Telles (2002) assessed autonomic variables on 35 male volunteers (20 to 46 years) in two sessions of yoga-based guided relaxation and supine rest. Assessments of autonomic variables were made for 15 subjects, before, during, and after the practices, whereas oxygen consumption and breath volume were recorded for 25 subjects before and after both types of relaxation. A significant decrease in oxygen consumption and increase in breath volume were recorded after guided relaxation (paired t test). There were comparable reductions in heart rate and skin conductance during both types of relaxation. During guided relaxation the power of the low frequency component of the heart-rate variability spectrum reduced, whereas the power of the high frequency component increased, suggesting reduced sympathetic activity. Also, subjects with a baseline ratio of LF/HF  $> 0.5$  showed a significant decrease in the ratio after guided relaxation, while subjects with a ratio  $\leq 0.5$  at baseline showed no such change. The results suggest that sympathetic activity decreased after guided relaxation based on yoga, depending on the baseline levels.

In 2004, Khalsa documented that although yoga is historically a spiritual discipline, it has also been used clinically as a therapeutic intervention. A bibliometric analysis on the biomedical journal literature involving research on the clinical application of yoga has revealed an increase in publication frequency over the past 3

decades with a substantial and growing use of randomized controlled trials. Types of medical conditions have included psychopathological (viz. depression and anxiety), cardiovascular (viz. hypertension, heart disease), respiratory (viz. asthma), diabetes and a variety of others. A majority of this research has been conducted by Indian investigators and published in Indian journals, particularly yoga specialty journals, although recent trends indicate increasing contributions from investigators in the U.S. and England.

Parshad (2004) describes that the state of the mind and that of the body are intimately related. If the mind is relaxed, the muscles in the body will also be relaxed. 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. In addition, the relaxation induced by meditation helps to stabilize the autonomic nervous system with a tendency towards parasympathetic dominance. Physiological benefits which follow help yoga practitioners become more resilient to stressful conditions and reduce a variety of important risk factors for various diseases, especially cardio-respiratory diseases.

Ghoncheh (2004) compared the psychological effects of **progressive muscle relaxation (PMR) and yoga stretching (hatha) exercises** taking 40 participants, randomly divided into two groups and taught PMR or yoga stretching exercises. Both groups practiced once a week for five weeks and were given the Smith Relaxation States Inventory before and after each session. As hypothesized, practitioners of PMR displayed higher levels of relaxation states (R-States) Physical Relaxation and Disengagement at Week 4 and higher levels of Mental Quiet and Joy as post training after effect at Week 5. Contrary to what was hypothesized, groups did not display

different levels of R-States Energized or Aware. Results suggest the value of supplementing traditional somatic conceptualizations of relaxation with the psychological approach embodied in ABC relaxation theory.

Jeong (2004) evaluated the effect of **progressive muscle relaxation (PMR)** training using biofeedback on perceived stress, stress response, immune response and climacteric symptoms. This was a crossover, pre-post test design. The study subjects are 36 middle-aged women who were selected at 2 public health centers. The independent variable was Biofeedback training for 4 weeks, twice a week and home training for 4 weeks. Dependent variables were perceived stress, stress response, immune response, and climacteric symptoms measured with Hildtch's scale (1996). PMR training using biofeedback was not effective in reducing perceived stress, but it was shown to be effective in reducing physiological stress responses such as pulse rate and EMG. PMR training using biofeedback was not effective in reducing serum cortisol, enhancing immune responses, or decreasing climacteric symptoms. The findings point to a pressing need for further, well-controlled and designed research with consideration in selection of subjects and instruments, frequency of measurements, the sampling method, and intervention modalities.

A study on **Hatha yoga and emotional distress** by Michalsen et al. (2005) evaluated the potential effects of Iyengar Hatha yoga on perceived stress and associated psychological outcomes in mentally distressed women. A controlled prospective non-randomized study was conducted in 24 self-referred female subjects (mean age 37.9+/-7.3 years) who perceived themselves as emotionally distressed. Subjects were offered participation in one of two subsequential 3-months yoga programs. Group 1 (n=16) participated in the first class, group 2 (n=8) served as a waiting list control. During the yoga course, subjects attended two-weekly 90-min

Iyengar yoga classes. Outcome was assessed on entry and after 3 months by Cohen Perceived Stress Scale, State-Trait Anxiety Inventory, Profile of Mood States, CESD-Depression Scale, Bf-S/Bf-S' Well-Being Scales, Freiburg Complaint List and ratings of physical well-being. Salivary cortisol levels were measured before and after an evening yoga class in a second sample. Compared to waiting-list, women who participated in the yoga-training demonstrated pronounced and significant improvements in perceived stress, State and Trait Anxiety, well-being, vigor, fatigue and depression. Physical well-being also increased, and those subjects suffering from headache or back pain reported marked pain relief. Salivary cortisol decreased significantly after participation in a yoga class. Women suffering from mental distress participating in a 3-month Iyengar yoga class showed significant improvements on measures of stress and psychological outcomes.

### **2.2.3 Summary**

- Effect of stress was reversed in significantly shorter time in *Shavasana*, compared to the resting posture in chair and a supine posture.
- It was concluded that group relaxation appeared to improve mental health scores effectively for both stressed and nonstressed adults and that age was significantly related to some personality scores.
- The results suggest that sympathetic activity decreased after guided relaxation based on yoga, depending on the baseline levels.
- Yoga therapy is a relatively novel and emerging clinical discipline within the broad category of mind-body medicine, whose growth is consistent with the burgeoning popularity of yoga in the West and the increasing worldwide use of alternative medicine.

- The relaxation induced by meditation helps to stabilize the autonomic nervous system with a tendency towards parasympathetic dominance. And the practitioners become more resilient to stressful conditions and reduce important risk factors for various diseases, especially cardio-respiratory diseases.
- Practitioners of PMR displayed higher levels of relaxation states (R-States) Physical Relaxation and Disengagement at Week 4 and higher levels of Mental Quiet and Joy
- PMR training using biofeedback was not effective in reducing perceived stress, in reducing serum cortisol, enhancing immune responses, or decreasing climacteric symptoms, but was only effective in reducing physiological stress responses.
- Women suffering from mental distress participating in a 3-month Iyengar yoga class showed significant improvements on measures of stress and psychological outcomes.

#### **2.2.4 Studies on physical exercise and climacteric syndrome**

Arai & Hisamichi (1998) studied an interesting relationship between personality and exercise frequency based on 22,448 residents (40 to 64 years old) in Miyagi, Japan. They completed the self-administered questionnaires on their exercise frequency and the Japanese version of the short form Eysenck's Personality Questionnaire-Revised. Higher scores on Extroversion were positively related to exercising and higher scores on Neuroticism and Psychoticism were positively related to "not exercising" in a general population for both sexes.

Williams & Lord (1997) conducted a randomised controlled trial to determine whether a 12-month program of group exercise had beneficial effects on physiological and cognitive functioning and mood in **187 older community-dwelling women**. The exercisers (n = 94) and controls (n = 93) were well matched in terms of the test measures and a number of health and life-style assessments. The mean number of classes attended by the 71 exercise subjects who completed the program was 59.0 (range 26 to 82). At the end of the trial, the exercisers showed significant improvements in reaction time, strength, memory span and measures of wellbeing when compared with the controls. There was also an indication that anxiety had been reduced in the exercisers. Within the exercise group, improvements in memory span were associated with concomitant improvements in both reaction time and muscle strength. Also, within this group, initial mood measures were significantly inversely associated with improvements at retest, which suggests that the program may have

normalised mood states in subjects who had high initial depression, anxiety and stress levels, rather than inducing improvements in all subjects.

Gaspard et al (2001) documented that in **postmenopausal women**, metabolic and cardiovascular risks are increased not only because of aging but also in relation to estrogen deprivation, decreased physical activity and dietary changes. Accordingly, an increase in total fat mass and its intra-abdominal component, a decrease in lean body mass, an atherogenic dyslipidemia, decreased glucose tolerance, insulin resistance and an increase in procoagulant factors are ensuing, in a manner similar to the metabolic syndrome X and its accompanying risk for cardiovascular disease. Physical exercise concurs with an appropriate diet to weight loss, increases lean body mass and altogether energy expenditure, decreases total body fat mass and visceral fat, improves insulin sensitivity, reduces fibrinogenemia and optimizes hemodynamic parameters. Additionally, physical exercise contributes to protecting bone mass and may be associated with a decreased risk of estrogen-dependent breast and endometrial carcinomas at the postmenopause.

Tworoger et al (2003) examined the effects of a moderate-intensity exercise or stretching intervention and changes in fitness, body mass index, or time spent outdoors on self-reported sleep quality and to examine the relationship between the amount and timing of exercise and sleep quality. A randomized intervention trial taking **postmenopausal**, overweight or obese, sedentary women not taking hormone replacement therapy, aged 50 to 75 years were recruited from the Seattle metropolitan area. Women underwent a yearlong moderate-intensity exercise (n=87) and a low-intensity stretching (n=86) program. Among morning exercisers, those who exercised at least 225 minutes per week had less trouble falling asleep compared with those who exercised less than 180 minutes per week. However, among evening exercisers, those

who exercised at least 225 minutes per week had more trouble falling asleep compared to those who exercised less than 180 minutes per week. Stretchers were less likely to use sleep medication and have trouble falling asleep during the intervention period compared with baseline. A greater than 10% versus a 1% or less increase in maximum O<sub>2</sub> consumption over the year was associated with longer sleep duration, less frequently falling asleep during quiet activities, and less use of sleep medication. Reductions in body mass index and increases in time spent outdoors had inconsistent effects on sleep quality.

Restrepo et al (2003) also evaluated the effect of a controlled physical activity program on the weight and body composition of healthy sedentary postmenopausal women. From a group of 138 **postmenopausal women** volunteers, 18 of them were selected, using a survey that measured the frequency and intensity of their physical activity. These 18 women were classified as "sedentary," having an average daily energy expenditure (in terms of ml of oxygen per kg per minute) that was below 60% of the maximum oxygen consumption for their age. These 18 women underwent a general physical examination, laboratory tests, and spirometry to make certain that they did not have illnesses that would prevent them from participating in the planned controlled physical activity program. The activity program lasted 4 months, with three one-hour sessions per week. Before and after the program the following characteristics were evaluated for each participant: weight, body fat, and the fatty area and the lean area of the arm, the thigh, and the leg. In addition, energy intake was determined based on a record of food consumption, with the frequency of the consumption of specific foods assessed semi quantitatively. At the end the program we found a reduction of 1.2 kg in weight and of 2.0 kg in body fat, while the lean mass increased by 1.0 kg. The differences were statistically significant for all the

variables observed except for the lean area of the thigh. There were no significant differences between the women's energy intake at the beginning and the end of the program. The controlled physical activity program improved the body composition of this group of women, decreasing the fat deposits and increasing the lean body mass.

Jeng et al. (2004) reported that menopausal women are at high risk for cardiovascular diseases and osteoporosis. However, for so long, women have devoted much of their time and energy to family, children, and work such that they could not regularly exercise. There are few studies addressing the experiences of **Taiwanese women** who regularly exercise. The aim of this study was to explore the experiences of regularly exercising, defined as thoughts or actions by menopausal women who did not regularly exercise before menopause, but who now exercise regularly. In-depth interviews were undertaken with a purposive sampling of 12 menopausal women who began to do regular exercises after menopause and who have continued exercising for more than 6 months. 'Perceiving Continuous Power' was the core category during the process of regularly exercising. Every participating woman perceived that her body and mind were filled with continuous power including the subcategories of 'Overcoming the initial discomfort', 'Experiencing Benefits to Body and Mind' and 'Broadening' during the process. 'Awareness of Health Crisis', which included the subcategories of 'Cureless Chronic Disease', 'Mood Swings', and 'Conflict on Medication', was identified as occurring when these women first began regularly exercising. Throughout the process of perceiving continuous power, women experienced the following interactive behavior categories: 'Exercise Selection' with subcategories of 'Self-Evaluation', 'Seeking and Fitting', 'Comparing' and 'Health Becoming' with the subcategories of 'Releasing Health Crisis', 'Regaining Flowering Life', and 'Self-Fulfilling'. Regular exercises provided continuous power for

menopausal women with their regular exercise plans. Asikainen et al. (2004) stated that because the recommendations are based mainly on studies on men. They conducted a systematic review for randomised, controlled exercise trials on postmenopausal women (aged 50 to 65 years) on components of HRF. Twenty-eight randomised controlled trials with 2646 participants were assessed. HRF consisted of morphological fitness (body composition and bone strength), musculoskeletal fitness (muscle strength and endurance, flexibility), motor fitness (postural control), cardio respiratory fitness (maximal aerobic power, blood pressure) and metabolic fitness (lipid and carbohydrate metabolism). The outcome variables chosen were: bodyweight; proportion of body fat of total bodyweight (F%); bone mineral density (BMD); bone mineral content (BMC); various tests on muscle performance, flexibility, balance and coordination; maximal oxygen consumption ( $\dot{V}O_{2max}$ ); resting blood pressure (BP); total cholesterol (TC); high-density lipoprotein-cholesterol; low-density lipoprotein-cholesterol; triglycerides; blood glucose and insulin. In total, 18 studies reported on the effects of exercise on bodyweight and F%, 16 on BMD or BMC, 11 on muscular strength or endurance, five on flexibility, six on balance or coordination, 18 on  $\dot{V}O_{2max}$ , seven on BP, nine on lipids and two studies on glucose and one on insulin. Based on these studies, early postmenopausal women could benefit from 30 minutes of daily moderate walking in one to three bouts combined with a resistance training programme twice a week. A feasible way to start resistance training is to perform eight to ten repetitions of eight to ten exercises for major muscle groups starting with 40% of one repetition maximum. The training described above is likely to preserve normal bodyweight, or combined with a weight-reducing diet, preserve BMD and increase muscle strength.

Milton et al. (2005) investigated the influence of personality on exercise-induced mood changes. It was hypothesized that a) exercise would be associated with significant mood enhancement across all personality types, b) extroversion would be associated with positive mood and neuroticism with negative mood both pre- and post-exercise, and c) personality measures would interact with exercise-induced mood changes. Participants were 90 female exercisers (M=25.8 y, SD=9.0 y) who completed the Eysenck's Personality Inventory once and the Brunel Mood Scale before and after a 60-min exercise session. Median splits were used to group participants into 4 personality types: stable introverts (n=25), stable extroverts (n=20), neurotic introverts (n=26), and neurotic extroverts (n=19). Neuroticism was associated with negative mood scores pre- and post-exercise but the effect of extroversion on reported mood was relatively weak. There was no significant interaction effect between exercise-induced mood enhancement and personality. Findings lend support to the notion that exercise is associated with improved mood. However, findings show that personality did not influence this effect, although neuroticism was associated with negative mood.

Thurston et al. (2006) examined whether physical activity was associated with decreased risk of **vasomotor symptoms** in a prospective study of women transitioning through **menopause**. Hypotheses were evaluated in the Harvard Study of Moods and Cycles, a longitudinal study of women with and without a history of major depression (N = 523). Ordinal logistic regression models were utilized to assess the odds of vasomotor symptoms (none, mild, moderate/severe; Greene Climacteric Scale) associated with physical activity (quartiles of metabolic equivalent-hours per week) at study enrollment and over a 3- to 5-year follow-up period. No significant associations between physical activity and vasomotor symptoms were observed for

the sample as a whole. However, exploratory analyses stratified by depression history revealed that among the 157 women with a lifetime history of major depression, high or moderately high physical activity proximal to the vasomotor assessment, as well as consistently high or increasing physical activity over the duration of the 3- to 5-year follow-up period was associated with decreased vasomotor symptoms relative to sedentary behavior.

#### **2.2.4 Summary**

- Higher scores on Extroversion were positively related to exercising and higher scores on Neuroticism and Psychoticism were positively related to "not exercising" in a general population for both sexes.
- Group exercise has beneficial effects on physiological and cognitive functioning and wellbeing in older people.
- In association with a balanced diet, and estrogen administration, physical exercise significantly contributes to metabolic fitness and decreased cardiovascular risk in postmenopausal women.
- Both stretching and exercise interventions may improve sleep quality in sedentary, overweight, postmenopausal women. Increased fitness was associated with improvements in sleep. However, the effect of moderate-intensity exercise may depend on the amount of exercise and time of day it is performed.
- The controlled physical activity program improved the body composition of this group of women, decreasing the fat deposits and increasing the lean body mass.
- Regular exercises provide continuous power for menopausal women with their regular exercise plans.

- The review on 28 studies randomised controlled trials in women who pass through menopause suggested that the physical training is likely to preserve normal bodyweight, preserve BMD and increase muscle strength, improve flexibility, balance and coordination, decrease hypertension and improve dyslipidaemia although these may not meet their specific needs.
- Physical activity may be associated with decreased risk of vasomotor symptoms among women with a history of major depression.

### **2.2.5 Studies on Hormone replacement therapy (HRT)**

Campbell & Whitehead (1977) took 64 patients with severe menopausal symptoms and completed a four month double-blind placebo trial with conjugated equine oestrogens (premarin). Using a graphic rating scale system of assessment, a statistically significant improvement with premarin was observed in 12 psychological and symptomatic scores. From a comparison between these results and the results of the 20 patients without vasomotor symptoms it would appear that many of these symptomatic improvements result from the relief of hot flushes (i.e. a domino effect). However, the improvement in memory and reduction of anxiety in these 20 patients suggest that oestrogens have a direct tonic effect on the mental state which is independent of vasomotor symptoms.

Sixty-one patients with less severe menopausal symptoms completed the second twelve month double-blind placebo trial and, as assessed by graphic rating scales, a significant improvement with premarin was observed in five psychological and symptomatic scores. In both the twelve and four month studies the marked placebo effect of "youthful skin appearance", and on skin greasiness in the twelve month study, indicate that no reliance can be placed on patient judgement of skin texture and appearance. The strength and duration of the placebo effect were well demonstrated in the three standard psychiatric scoring systems, the Beck score (for depression), the General Health Questionnaire and the Eysenck's Personality Index (formula: see text) (for neuroticism). A highly significant placebo effect extending for six months in all three was observed, the improvement with premarin over placebo

being non-significant. It was concluded these tests are not sufficiently sensitive to assess psychological or symptomatic changes in menopausal women and that these changes are best assessed by the graphic rating scales. The number of side-effects and complications was assessed in the 61 patients in the long study. A higher incidence of minor side-effects was observed during premarin therapy; this was most marked in relation to leg cramps but radio-isotope scanning revealed no evidence of leg vein thrombosis in these patients or indeed in any patient in the study.

Collins et al. (1994) examined the reproductive health, use of estrogen, lifestyle, experience of menopausal symptoms and work-role related issues in a population-based sample of perimenopausal women. All women aged 48 years and residing in the catchment area of the Karolinska Hospital were recruited through the Swedish population register. They received a questionnaire covering sociodemographic background, reproductive health and gynaecological characteristics, social and work role related issues as well as a symptom rating scale. Seventy percent of the women returned the questionnaire. Of these, 73% were premenopausal, 21% were postmenopausal and 6% were perimenopausal. Hormone replacement therapy was used by 7.5% of the respondents and the rate of hysterectomy was 8.6%. Regular exercise was reported by 44.4%. Multiple regression analyses showed that only vasomotor symptoms were significantly related to menopausal status. Negative Mood and Reduced Sexual Interest were better explained by the presence of vasomotor symptoms and by reproductive health and lifestyle variables such as current or previous PMS, dysmenorrhea, smoking and lack of exercise.

Gramegna et al. (1996) report that the psychological effects of estrogen supplement are not well documented. Hence they studied the effects of estrogen

supplementation on psychological variables in climacteric women. Forty postmenopausal women were divided in two groups to receive a daily dose of 2 mg oestradiol valerate and 2.5 mg medroxyprogesterone acetate or an identical placebo during six months. Initially and at the end of the treatment period, they were subjected to a psychiatric interview and the Graffar, Hamilton and Eysenck personality tests were applied. Also, an Analysis of Verbal Behavior was used, that results in hope and hopeless scores. There were no differences in the initial assessment between the two treatment groups. In women receiving hormonal supplementation, the Hamilton score decreased from 11.2 to 4.9 and in women receiving placebo from 8.1 to 5.3 (NS). No other significant changes in psychological tests were observed.

Lucero & McCloskey (1997) state that postmenopausal women experiencing hot flashes in whom estrogen replacement is contraindicated have alternatives available to them; however, there is no clearly defined treatment modality. The literature addressing many of these alternatives has serious limitations, which include the small number of women enrolled and lack of comparative studies between agents. Each patient needs to be assessed in terms of her current medical status, concomitant medications, and the degree to which vasomotor instability interferes with everyday activities. The literature suggests that megestrol acetate 20 mg bid may provide significant relief. Women who opt to use megestrol acetate must be told in advance that the effects will not be felt immediately particularly if tamoxifen is used concomitantly. Clonidine and medroxyprogesterone may constitute potential alternatives, but patients may not be able to tolerate the adverse effects. Because of the lack of literature supporting their clinical use, options such as vitamin E and ginseng need to be approached cautiously. Exercise has a role in alleviating some of the complications associated with menopause, such as heart disease and osteoporosis,

but its effect on neurotransmitters and hormone concentrations, and how this relates to the treatment of hot flashes have not been characterized. Patients should be told that regular physical activity, a balanced diet, avoidance of alcohol and caffeine, and stress reduction may be of additional help in decreasing vasomotor flushing.

Tinelli et al (2003) reported that the ovarian failure and the termination of reproductive female functions could influence the mental neurotransmission and the cognitive activity of menopausal women; female menopausal brain, one of the favorite estrogens target, could suffer of a negative homeostasis modification, affecting the daily behavior. So, neurotransmissive degeneration could expose aged women to some psychological disturbances, some of these frequently associated to hypoestrogenic hot flushes rise. Many studies showed the estrogen influence on female brain, and tried to explain how the hormonal replacement therapy (HRT), act on mood, life energy and cognitive activities. Although brain estrogenic activity seems to establish a useful role on neuromodulation and on the prevention of some psychopathologies, the conventional administration of HRT, improves the mood and menopausal female well-being, but it does not act on clinically depressed women.

Barrett-Connor et al (2005) reported the risk involved in estrogen therapy. In the Women's Health Initiative controlled clinical trials, both estrogen therapy (ET) and estrogen plus progestin therapy (EPT) reduced fracture risk, neither reduced the risk of heart disease, and both increased the risk of stroke, deep vein thrombosis, and dementia. EPT, but not ET, increased breast cancer risk and reduced colon cancer risk. Differences between EPT and ET may reflect chance, baseline differences between the EPT and ET cohorts, or a progestin effect.

### **2.2.5 Summary**

- The improvement in memory and reduction of anxiety in menopausal patients suggest that oestrogens have a direct tonic effect on the mental state which is independent of vasomotor symptoms.
- A higher incidence of minor side-effects and leg cramps with no leg vein thrombosis was observed during Premarin therapy; hormonal supplementation decreases the Hamilton depression score in postmenopausal women.
- For postmenopausal women experiencing hot flashes in whom estrogen replacement is contraindicated Clonidine and medroxyprogesterone may constitute potential alternatives, but patients may not be able to tolerate the adverse effects.
- Although many studies showed the estrogen influence on female brain, and tried to explain how the hormonal replacement therapy (HRT), act on mood, life energy and cognitive activities it does not act on clinically depressed women.
- Women's Health Initiative controlled clinical trials report estrogen therapy (ET) and estrogen plus progestin therapy (EPT) reduced fracture risk, neither reduced the risk of heart disease, and both increased the risk of stroke, deep vein thrombosis, and dementia. EPT, but not ET, increased breast cancer risk and reduced colon cancer risk.

### **2.2.6 Studies on complementary and alternative therapies**

The National Center for Complementary and Alternative Medicine at the National Institutes of Health defines alternative therapies as "those treatments and health care practices not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies" (<http://nccam.nih.gov/>). A national survey found that 42.1% of US adults used some type of alternative therapy in 1997, with 46.3% making visits to alternative providers at an estimated \$27 billion in total annual out-of-pocket expenditures (Eisenberg et al 1998). Alternative and complementary therapies are most widely used for chronic conditions (Eisenberg et al 1998). Many therapies, including dietary soy (Murkies et al, 1995; Quella et al, 2000; St Germain et al, 2001; Nagata et al, 2001; Washburn et al, 1999; Albertazzi et al, 1998) isoflavone supplements (Scambia et al, 2000; Upmalis et al, 2000; Vincent & Fitzpatrick, 2000; NAMS Consensus, 2000), herbs such as black cohosh (Hardy, 2000; Jacobson et al, 2001), and acupuncture (Wu et al, 1998) have been proposed for the relief of menopause symptoms, but the prevalence of use of such therapies for this purpose is unknown.

Katherine (2002) described self-reported prevalence of the use of alternative therapies for menopause symptoms and subject characteristics associated with their use. A telephone survey of 886 women aged 45–65 years (87.2% response rate) was conducted at Group Health Cooperative in Washington. Women were asked about eight alternative therapies and their use for menopause symptoms. The proportion of women who used each therapy was 76.1% for any therapy, 43.1% for stress

management, 37.0% for over-the-counter alternative remedies, 31.6% for chiropractic, 29.5% for massage therapy, 22.9% for dietary soy, 10.4% for acupuncture, 9.4% for naturopath or homeopath, and 4.6% for herbalists. Among women who used these therapies, 89–100% found them to be somewhat or very helpful. A history of breast cancer was associated with a six-fold increase in use of dietary soy for menopause symptoms. Current users of HRT were half as likely to use alternative remedies or providers as were never users. Sleep disturbances were associated with a four-fold increase in the use of body work, a three-fold increase in the use of stress management, and more than doubled the use of dietary soy products to manage menopause symptoms.

Eller (1999) made a review which focuses on 46 studies of the use of guided imagery intervention studies identified in the nursing, medical and psychological literature published between 1966 and 1998 for management of psychological and physiological symptoms. There is preliminary evidence for the effectiveness of guided imagery in the management of stress, anxiety and depression, and for the reduction of blood pressure, pain and the side effects of chemotherapy. Overall, results of this review demonstrated a need for systematic, well-designed studies, which explore several unanswered questions regarding the use of guided imagery. For the past several decades, papers in the nursing literature have advocated the use of cognitive interventions in clinical practice.

Gimbel (1998) documents Hatha yoga and meditation as adjunctive therapies for promoting and maintaining wellness offer an excellent example of the mind-body connection at work. Hatha yoga creates balance, physically and emotionally, by using postures, or asanas, combined with breathing techniques, or pranayama. Meditation and guided imagery not only support the physical and emotional work being done by

the postures and breathing, they open the door to self-actualization to create the perfect union of the mind, body, and spirit.

Hudetz et al. (2000) tested the hypothesis that relaxation by guided imagery improves working-memory performance of healthy participants. 30 volunteers (both sexes, ages 17-56 years) were randomly assigned to one of three groups and administered the WAIS-III Letter-Number Sequencing Test before and after 10-minute treatment with guided imagery or popular music. The control group received no treatment. As hypothesized, the mean increased after relaxation in the guided imagery group but not in music group or no-treatment group. Thus the result supports the hypothesis that working-memory scores on the test are enhanced by guided imagery and implies that human information processing may be enhanced by prior relaxation.

Shang (2001) expressed the emerging paradigms in medicine that can be seen through mind-body interactions. Observations in many meditative traditions suggest a series of objective indicators of health beyond absence of disease. Several of the physical signs have been confirmed by research or are consistent with modern science. Further correlation with long term health outcome is needed. Integration of meditation with conventional therapy has enriched psychotherapy with parallels drawn between the Nine Step Qigong and Freudian developmental psychology. A unified theory of the chakra system and the meridian system widely used in traditional mind-body interventions and acupuncture is presented in terms of modern science based on the morphogenetic singularity theory. Acupuncture points originate from the organizing centers in morphogenesis. Meridians and chakras are related to the under differentiated, interconnected cellular network that regulates growth and physiology. This theory explains the distribution and nonspecific activation of organizing centers

and acupuncture points; the high electric conductance of the meridian system; the polarity effect of electroacupuncture; the side-effect profile of acupuncture; and the ontogeny, phylogeny, and physiologic function of the meridian system and chakra system. It also successfully predicted several findings in conventional biomedical science. These advances have implications in many disciplines of medicine.

Interest in use of alternative remedies for managing menopausal symptoms is increasing exponentially during these years. Chen et al (2003) performed a randomized, controlled pilot study to evaluate the clinical effects of Jia-Wey Shiau-Yau San (JWSYS), one of the traditional Chinese herbal prescriptions, a famous herbal remedy used for the management of various menopausal-related symptoms compared with those of a continuous combined hormone replacement therapy, Premelle, on quality of life in non-hysterectomized postmenopausal women. The present trial compared the effect of a 16-week treatment with JWSYS or HRT (Premelle) in postmenopausal women with climacteric symptoms. The Greene Climacteric Scale was used to assess the clinical effects at baseline and after 16 weeks' treatment with either JWSYS or Premelle. The results showed that JWSYS had a relatively lower discontinuation rate due to adverse effects, in particular the bleeding and breast tenderness. Both JWSYS and Premelle effectively alleviated most of the menopausal symptoms with no significant differences between treatment groups, whereas the beneficial effects of JWSYS were not mediated by hormone replacement-like effects. Moreover, JWSYS showed a good compliance and safety without estrogenic effects and metabolic alterations. It was suggested that JWSYS was a safe and efficacious therapy and might be an alternative choice for relief of climacteric symptoms in postmenopausal women.

Sun (2003) conducted a study to determine the efficacy of a morning/evening menopause formula (morning capsule contains panax ginseng, black cohosh, soy, and green tea extracts; evening capsule contains black cohosh, soy, kava, hops, and valerian extracts) for relieving menopausal symptoms such as hot flashes and sleep disturbance. Healthy postmenopausal women, between 45 and 65 years of age, were asked to take the menopause formula orally, one capsule of the morning formula every morning and one capsule of the evening formula every evening for 2 months. The Greene Climacteric Scale (GCS) and the Pittsburgh Sleep Quality Index (PSQI) were used to determine the efficacy. Morning/evening menopause formula significantly reduced the number of hot flashes. The reduction in the number of hot flashes was observed as early as at the end of the second week. At the end of the second week, the number of hot flashes was reduced by 47%. The morning/evening menopause formula also significantly reduced the GCS total and subscale scores. At the end of the eighth week, the vasomotor, anxiety, and depression scores of GCS were reduced by 50%, 56%, and 32%, respectively. Furthermore, the morning/evening menopause formula significantly reduced global PSQI score and scores in five components (sleep quality, sleep latency, sleep duration, sleep disturbance, and daytime dysfunction) by 18%-46%. This study suggests that the morning/evening menopausal formula is safe and effective for relieving menopausal symptoms including hot flashes and sleep disturbance.

Keefer & Blanchard (2005) tested the effectiveness of a cognitive-behavioral group treatment (CBGT) for hot flashes in menopausal women. Treatment was administered over 8, 90 min weekly sessions and consisted of education, relaxation training and cognitive restructuring. Nineteen women meeting STRAW staging criteria for the menopause transition (stages -1 to +1) were randomly assigned to

immediate or delayed treatment (wait list) and were asked to monitor their hot flashes and night sweats prospectively. They also completed questionnaires, including the Women's Health Questionnaire and the Menopause Specific Quality of Life Questionnaire to determine psychosocial benefits of treatment. Results suggested that the CBGT was moderately successful in reducing the frequency of total vasomotor symptoms, as measured by daily symptom diaries. While there were arithmetic improvements in psychosocial functioning in this sample, these results were not significant. Despite the limitations of small sample size and possible placebo effect, this pilot study supports the notion that cognitive-behavioral interventions aimed at reducing vasomotor symptoms may be of value for menopausal hot flashes when administered in a small-group format.

Daley et al. (2006) stated that hormone replacement therapy (HRT) is now thought to have serious adverse effects; consequently, many menopausal women are seeking to use complementary and alternative medicine (CAM), including non-pharmacological interventions (NPI), to alleviate symptoms. The prevalence and perceived effectiveness of CAM and NPI for ameliorating menopausal symptoms are not widely known and factors likely to predict CAM and NPI utilization for menopausal symptom management have not been comprehensively documented. With this, Daley et al. (2006) aimed to (1) determine the prevalence of using CAM and NPI for menopausal symptoms; (2) describe the perceived effectiveness of CAM and NPI for symptom management; and (3) investigate lifestyle and demographic factors associated with CAM/NPI use among menopausal women with vasomotor symptoms. Women aged 46-55 years were recruited via six socioeconomically diverse general practices. Participants completed a postal questionnaire that contained items relating to demographics, lifestyle factors, weight, height, exercise behavior, menopausal

status, vasomotor symptoms and utilization and perceived effectiveness of a range of CAM/NPI for symptom management. Of 1,206 women who responded, 563 (47%) were symptomatic. The most commonly used CAM/NPI for symptom management were diet/nutrition (44.3%), exercise/yoga (41.5%), relaxation/stress management (27.4%) and homeopathic/naturopathic remedies (25.4%). Of women who used these interventions, large proportions reported them to be helpful. The characteristics that were independently associated with use of CAM/NPI were White ethnicity, being physically active, and not smoking.

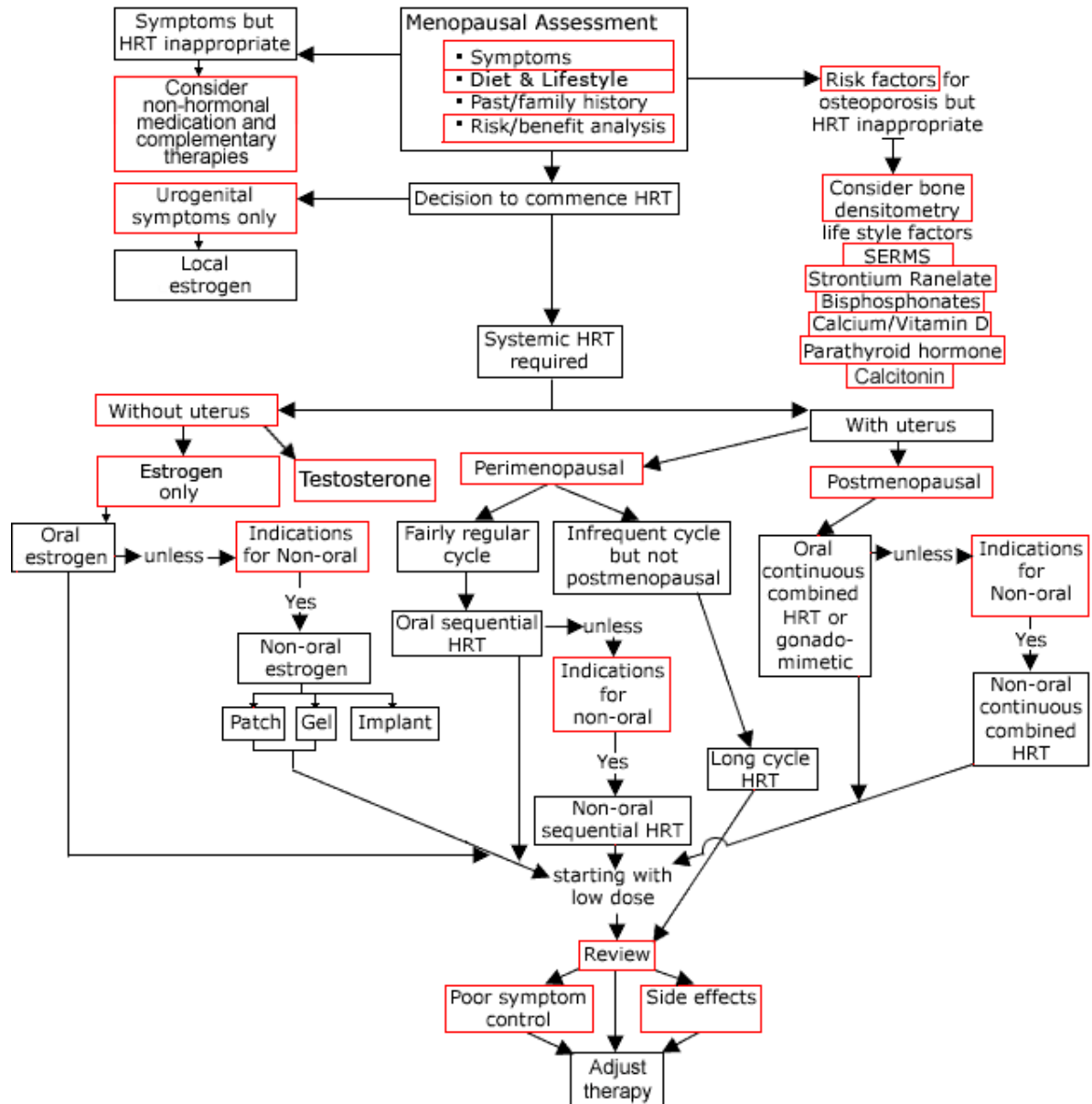
### **2.2.6 Summary**

- Many therapies previously considered "alternative" are gaining mainstream acceptance, and some states have mandated that insurance companies cover their use.
- Alternative and complementary therapies are most widely used for chronic conditions.
- A history of breast cancer was associated with a six-fold increase in use of dietary soy for menopause symptoms. Current users of HRT were half as likely to use alternative remedies or providers as were never users.
- Sleep disturbances were associated with a four-fold increase in the use of body work, a three-fold increase in the use of stress management, and more than doubled the use of dietary soy products to manage menopause symptoms. Physicians should routinely ascertain perimenopausal women's use of alternative therapies.
- 46 guided imagery intervention studies published between 1966 and 1998 for management of psychological and physiological symptoms show the effectiveness of guided imagery in the management of stress, anxiety and depression.

- Increasing consumer use of complementary therapies, a cost-driven health care system, and the need for evidence-based practice all lend urgency to the validation of the efficacy of these interventions.
- Hatha yoga and meditation together can serve as adjunctive therapies for promoting and maintaining wellness offer an excellent example of the mind-body connection at work.
- The working-memory scores on the test are enhanced by guided imagery and implies that human information processing may be enhanced by prior relaxation.
- Observations in many meditative traditions suggest that the chakra system and the meridian system widely used in traditional mind-body interventions and acupuncture are related to the under-differentiated, interconnected cellular network that regulates growth and physiology.
- Jia-Wey Shiau-Yau San (JWSYS), one of the traditional Chinese herbal prescriptions was a safe and efficacious therapy and might be an alternative choice for relief of climacteric symptoms in postmenopausal women.
- Morning/evening menopause formula significantly reduced the number of hot flashes, GCS total and subscale scores, global PSQI score and scores in five components (sleep quality, sleep latency, sleep duration, sleep disturbance, and daytime dysfunction) by 18%-46%. This suggests that the morning/evening menopausal formula is safe and effective for relieving menopausal symptoms.
- Cognitive-behavioral group treatment (CBGT) was moderately successful in reducing the frequency of total vasomotor symptoms. CBGT aimed at reducing vasomotor symptoms may be of value for menopausal hot flashes when administered in a small-group format.

- Many menopausal symptomatic women are using a wide range of CAM/NPI and report these to be effective, particularly those who are white, physically active and do not smoke.

From - <http://www.menopausematters.co.uk/tree.php>



### **3. AIMS & OBJECTIVES**

#### **AIMS**

1. To compile the available literature from yoga traditional scriptures on menopause
2. To study the content validity of Menopause Rating Scale and Greene Climacteric Scale in Indian population
3. To conduct an experimental study on the psychological, cognitive and physiological functions after yoga practices through a randomized control trial in perimenopausal women.

#### **OBJECTIVES of the study:**

1. To get insights into the understanding of the problems and management of climacteric as portrayed in Ayurveda texts.
2. To evaluate the content validity of Menopause Rating Scale and Greene Climacteric Scale through factor analysis so that it becomes a valid tool for future studies on climacteric in Indian population.
3. To study the changes in the vasomotor symptoms in perimenopausal women after 8 weeks of integrated approach to yoga therapy (IAYT).
4. To examine the cognitive (specifically memory and attention span) functions after 8 weeks of IAYT.
5. To study the psychological wellbeing after 8 weeks of IAYT.
6. To assess the autonomic functions after 8 weeks of IAYT.

## **HYPOTHESIS**

### **STUDY – 1**

There was no hypothesis testing involved in the study – 1.

### **STUDY – 2**

The study hypothesized that the IAYT practice would improve the vasomotor, cognitive and psychological and autonomic functions in symptomatic south Indian menopausal women.

## **4. METHODS**

### **4.1 Subjects**

**4.1.1 Study 1 - Cohort study to validate Menopause Rating Scale and Greene Climacteric Scale.**

**4.1.1a Participants and sampling**

**4.1.2 Study 2 - RCT to study the efficacy of IAYT in climacteric syndrome.**

**4.1.2a Participants and sampling**

**4.1.2b Inclusion criteria**

**4.1.2c Exclusion criteria**

**4.1.2d Source of the subjects**

**4.1.2e Signed informed consent**

### **4.2 INTERVENTION**

**4.2.1 Yoga group intervention**

**4.2.1.1 Cyclic meditation (*Avartan dhyan*)**

**4.2.1.2 Sun salutation (*Surya Namaskara*)**

**4.2.1.3 Breathing exercises**

**4.2.2 Control group intervention**

**4.2.2.1 Physical exercise**

### **4.3 VARIABLES ASSESSMENT**

**4.3.1 Biochemical assessment**

**4.3.2 Climacteric symptom assessment**

#### **4.3.2.1 Menopause Rating Scale**

#### **4.3.2.2 Greene Climacteric scale**

### **4.3.3 Cognitive assessments**

#### **4.3.3.1 Six-letter cancellation test**

#### **4.3.3.2 Punit Govil intelligence memory scale**

### **4.3.4 Psychological assessments**

#### **4.3.4.1 Perceived Stress Scale**

#### **4.3.4.2 Eysenck's Personality Inventory**

## **4.1 Subjects**

### **4.1.1 Study 1 - Cohort study to validate Greene Climacteric scale.**

The Indian subcontinent is a mix of many ethnic groups and cultures where perception of menopause varies (IMS-webpage, 2003). The average age of Indian menopausal women is 47 years (Padubidri et al, 2004). Since the average life span of women in India is now estimated to be 62 years, the problems of menopause have attained a greater significance (WHO, 2003) and are emerging as an issue owing to rapid urbanization (Sengupta, 2003). 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).

Till date, several instruments have been designed to measure and assess symptoms during this phase and the early instruments like the Blatt Menopausal Index, the Kupperman Index, the Menopause Checklist of Neugarten & Kraines (Blatt et al, 1953; Kupperman et al, 1953; Neugarten & Kraines, 1965) were the first widely used instruments to assess menopausal symptoms, now these have been largely replaced by the Greene Climacteric Scale and the Menopause Rating Scale (Greene, 1998; Heinemann et al, 2003). Attempts to delineate symptoms characteristic of menopausal phase of the climacterium have resulted in considerable debate.

Standardized menopause-specific instruments which measure symptoms of the climacteric need to have sound psychometric properties and must demonstrate construct validity for different populations of women. The elucidation of the internal structure of the Menopause Rating Scale (MRS) through factor analyses has been largely for western populations so far. The only study for an Asian population seems to be a study for women in Indonesia. This paper presents a factor analysis of the MRS for menopausal women in India.

A standard climacteric scale, now called the Greene Climacteric Scale (GCS) was developed by Greene in 1998, which independently measures psychological, somatic and vasomotor symptoms. In the light of our results, it is of relevance to briefly consider the history and construction of the GCS.

The purpose to use Greene Climacteric Scale (GCS) was to provide a brief but comprehensive and valid measure of climacteric symptomatology. The Scale can be, and has been used, to assess changes in different categories of symptoms in response to treatment interventions; in clinical trials of hormone replacement therapy; in comparative studies of different groups of women; in epidemiological studies and in basic research into the etiology of climacteric symptoms.

The development of the GCS, a scale of 21 items, was motivated by the examination of seven separate studies in which the number of items on the scale to assess the climacteric varied considerably (from 17 to 36). Greene (1976) initially conducted a factor analysis on a list of 30 symptoms reported by women aged 40-55 using a 30 item questionnaire in the United Kingdom. He identified three symptom clusters and labeled them as vasomotor, somatic and psychological. This was followed by an analysis on an Indian population by Indira and Murthy (1980) who also used the same 30 item questionnaire and found eight factors. Other studies

(Hunter et al, 1986; Holte & Mikkelson, 1991; Kaufert & Syrotuik, 1981; Mikkelson & Holte, 1982; Abe et al, 1984) found between four and seven factors. The items in these latter studies however were not the same as the 30 items of Greene's original questionnaire, though they were similar. Greene formulated his 21 item scale (the GCS) by retaining 16 items of his original scale, adding four items based on the later studies and adding one item on loss of sexual interest. This composite scale of 21 items (Appendix-III) is the one that is studied in this paper. The major change in perception of the climacteric between the original 30 item questionnaire and the instrument now called the GCS was that the factor that Greene (and others) had labeled as psychological was recognized to be a composite of two factors identified as "anxiety" and "depression" (Greene, 1998). The additional item on "loss of sexual interest" was added as a probe item, whose status was left for later evaluation.

The goal of this part of the study was to explore the factor structure of the 11 item Menopause Rating Scale (MRS) and 21 item Greene Climacteric Scale (GCS) in Indian women. This was part of a larger study whose aim was to aid menopausal women alleviate their symptoms.

#### **4.1.1a Participants and sampling**

This cohort study comprised 518 Indian women who satisfied the inclusion criteria of age between 45-55 years. Women who had undergone hysterectomy with retained ovaries were also included. Women unfamiliar with spoken English, with less than high school education, women taking hormone replacement therapy (HRT), with gynecological problems like endometriosis, fibroids, ovarian cysts, prolapsed uterus etc, or with other medical disorders (like Hypertension, Diabetes Mellitus, Hypo / Hyperthyroidism) and those on psychiatric medication were excluded from the study.

The study was conducted at Swami Vivekananda Yoga Research Foundation (SVYASA), a yoga university, Bangalore, India. Formal approval for the study was obtained by the institutional review board and the ethical committee of the university. The data was collected from various places (banks, staff of schools and colleges, ladies clubs and gynecology outpatient clinics). The women who satisfied the inclusion criteria were registered and signed informed consent was obtained. The participants were requested to fill the Menopause Rating Scale and the Greene Climacteric Scale, they were assured that their responses would be kept confidential.

#### ***The Menopause Rating Scale (MRS)***

The Menopause Rating Scale (Appendix-IV) is intended to be a simple scale that can be easily filled in by women and consists of a list of 11 symptoms that are to be rated by the subject on a scale of 0 (no symptoms); (1) mild; (2) moderate; (3) severe; (4) very severe symptoms. The total score can therefore range from 0 (asymptomatic) to 44 (the highest severity of symptoms). The symptoms are related to Somatic, psychological and uro-genital problems in the climacteric ([www.menopause-rating-scale.info](http://www.menopause-rating-scale.info)).

#### ***The Greene Climacteric Scale (GCS)***

The Greene Climacteric Scale measures a total of 21 symptoms (Appendix-III). Each symptom is rated by the woman herself according to its current severity using a four-point rating scale: not at all (0); a little (1); quite a bit (2) and extremely (3). The symptoms are related to psychological (anxiety and depression), somatic and vasomotor functions in the climacteric.

#### **4.1.2 Study 2-Randomised control trial to evaluate the efficacy of yoga in climacteric syndrome.**

This was a prospective randomised control trial wherein two hundred and one women were screened; one hundred and twenty were recruited according to the inclusion and exclusion criteria and were randomly divided into two study arms; one arm practiced integrated approach of yoga therapy (IAYT) and the other arm practiced a set of physical exercises for 8 weeks. The women from different nodal centers who satisfied the inclusion criteria were registered, roll numbers were allotted and these numbers were randomly divided into two groups using a computer generated random number table ([www.randomizer.org](http://www.randomizer.org)) prepared for the specific number of participants available in the centre. Participants were assessed for the cognitive tests (SLCT and PGIMS), psychological symptoms (EPI and PSS), menopausal symptoms (GCS and MRS) before and after the 8<sup>th</sup> week of intervention. Both yoga and control groups were given their respective set of practices for one hour of intervention per day, 5 days per week for 8 weeks, by SVYASA trained instructors for both yoga and non yoga practice groups.

##### ***Blinding:***

As this is an interventional study this could not be a double blind study but attempts were made to blind and mask wherever feasible to reduce the bias. The statistician who did the randomization of the serial numbers of participants and the final analysis was blind to the source of the data. The response sheets for the SLCT, PGIMS, EPI, PSS, GCS and MRS were coded and kept away for final analysis and were decoded only after complete analysis. The memory tests were administered by a psychologist (who was not involved in interacting with the participants) to the whole group before randomization. Care was taken to arrange the timings and venue of the classes for the

two groups suitably to avoid interaction and exchange of information and techniques between participants of the two groups.

#### 4.1.2a Participants and sampling

The sample size was calculated from a study comparing the effects of two different drugs on menopausal women. The ‘ $\alpha$ ’ and power was fixed 0.05 and 0.8 respectively. The effect size (0.52) was calculated taking the pre post mean and SD values from the vasomotor outcome variable from an original research paper (Chen et al, 2003).

*Effect size calculation:*

$S_b$  = Std. dev before             $S_a$  = Std. dev after

$$S_d = \sqrt{S_a^2 + S_b^2 - 2r_{ab} S_a S_b}$$

where  $r_{ab}$  = Correlation Coefficient between After and Before data.

$$S_d \text{ before} = 1.74$$

$$S_d \text{ after} = 1.11$$

$r$  = not known, so assumed 0

$$S_d \text{ of the difference} = 2.05$$

$$d = \frac{X_a - X_b}{S_d}$$

$$S_d$$

where  $X_a$  : mean of after data

$X_b$  : mean of before data

$$d = \frac{2.33 - 1.25}{2.05}$$

$$= \frac{1.08}{2.05}$$

$$= \frac{1.08}{2.05} = 0.52$$

$$2.05$$

*Sample size calculation:*

Effect size = 0.52

Power = 0.95 (the probability to reject the null hypothesis)

$\alpha = 0.05$ ,  $\beta = 0.05$

After inserting all these required values in Gpower, the formula used to calculate

$$n = \frac{1}{d^2} (t_{\alpha(2),v} + t_{\beta(1),v})^2$$

Where v denotes degrees of freedom

Sample size:  $54 + 54 = 108$

The sample size came out to be 108.

Out of a total of two hundred and one women (experiencing menopausal symptoms) screened, one hundred and twenty women between 40 to 55 years (married or single) satisfied the inclusion criterion.

#### **4.1.2b Inclusion criteria**

(a) Follicle stimulating hormone (FSH) >15mIU/ml in blood serum (by Electro chemiluminescence's method in Anand Diagnostic laboratory, Bangalore) on the 6<sup>th</sup> day of the subject's menstruation if she was menstruating regularly and if she had stopped menstruating or had irregularity of menstruation cycles, she underwent the FSH test at the time of recruitment itself.

(b) Women who had undergone hysterectomy with retained ovaries were also included.

#### **4.1.2c Exclusion criteria**

- (a) Women who were practicing yoga from a month or more
- (b) Women who were non - English speaking
- (c) Women with less than high school education
- (d) Women from a low-income group were excluded from the study
- (e) Women taking hormone replacement therapy (HRT)
- (f) Women who underwent any surgery in past 3 months
- (g) Those with having gynecological problems (like endometriosis, fibroids, ovarian / uterus cysts, prolapsed uterus)
- (h) Women with other medical disorders (like Hypertension, Diabetes Mellitus, Hypo / Hyperthyroidism) and
- (i) Those on psychiatric medication were excluded from the study.

#### **4.1.2d Source of the subjects**

The study was conducted in Swami Vivekananda Yoga Research Foundation (SVYASA), Yoga University, Bangalore. Participants were recruited from gynecological outpatient clinics in 14 different areas of Bangalore through banners, newspaper advertisements and circulation of pamphlets apart from references through word of mouth. Classes were conducted at 14 nodal centers of SVYASA in different parts of the city.

#### **4.1.2e Signed informed consent**

Ethical clearance and consent: Formal approval was obtained by the institutional review board (IRB) and ethical committee of the SVYASA University, Bangalore.

Signed informed consent was taken by the each participant before their recruitment after clarifying all their doubts about the design of the study.

## **4.2 INTERVENTION**

### **4.2.1 Yoga group intervention**

#### **4.2.1.1 Cyclic meditation (*Avartan dhyan*)**

#### **4.2.1.2 Sun salutation (*Surya Namaskara*)**

#### **4.2.1.3 Breathing exercises**

### **4.2.2 Control group intervention**

#### **4.2.2.1 Physical exercise**

## **4.2 INTERVENTION**

### **4.2.1 Yoga group intervention**

The yoga module used for the experimental intervention called Integrated approach of yoga therapy (IAYT) for perimenopausal women was developed specifically for the purpose culled out from original scriptures (*Patanjali yoga sutras, and Mandukya karika*) that highlight the concepts of a holistic approach to health management at physical, mental, emotional and intellectual levels with techniques to improve mental equilibrium and cognitive abilities. All these practices are aimed at one common effect i.e. ‘to develop mastery over modifications of the mind’ (*chitta vritti nirodhah - Sage Patanjali*) through ‘slowing down the rate of flow of thoughts in the mind’ (*manah prashamana upayah yogah - Sage Vasishta*).

#### **4.2.1.1 Cyclic meditation (*Avartan dhyan*)**

Meditation is considered to be a part of yoga that works directly at the mind level (*Antaranga yoga*) which is a valuable tool to reach a state of alertful rest (calming down or silencing the internal dialogue). Cyclic meditation is a 30 minute practice that includes a combination of activating and pacifying practices to reach deeper

quietitude and equilibrium than meditating in a single posture (Sarang & Telles, 2007). In the Cyclic Meditation practice, participants were instructed to keep their eyes closed, and follow the instructions. The instructions emphasized carrying out the practice very slowly, with pointed as well as expanded awareness and relaxation. The practice began by reciting a verse from the yoga text, the *Muṇḍūkya Upaniṣat* (Chinmayananda, 1984); followed by isometric contraction of the muscles of the entire body ending with supine rest for about 1 minute; slowly coming up from the left side and standing at ease (called *Tāḍāsana*) and ‘balancing’ the weight on both feet, called centering for 2:00 minutes; then the first posture, bending to the right (*Aardhakaṭīcakrāsana* for 1:30 minutes); a gap of 1:30 minutes in *tāḍāsana* with instructions about relaxation and awareness; bending to the left (*Ardhakaṭīcakrāsana* for 1:30 minutes); a gap before (1:30 minutes); forward bending (*Pādahastāsana* for 1:30 minutes); another gap (1:30 minutes); then they slowly bend their knees and came to sitting position with legs stretched in front, slowly they folded legs and seated themselves on their heels (*Vajrasana* for 30 seconds); they stood up on the knees and slowly bend backwards supporting the waist with their hands (*Uṣṭrasana* for 1:00 minutes) for stimulating their back; then slowly released the posture and came down to lying position. Then they practiced quick relaxation technique (QRT for 5 minutes) in supine posture for relaxing the back; again came up straight with elbow’s support to sitting position (*Vajrasana*) and held their right wrist with the left palm, bending forward until the head touched the floor (*Shashankasana* for 1:30 minute) for stimulating the back again; then slowly released the posture and went again straight back to supine position (*Shavasana*) for Deep relaxation technique with instructions to relax different parts of the body in sequence (15:00 minutes). The session closed with

the *shanti paath* (peace verse). The postures were practiced slowly, with awareness of all the sensations that are felt. The total duration of the practice was 30:00 minutes. The key features of cyclic meditation are (i) postures interspersed with relaxation, (ii) slowness of movements, (iii) continuity, (iv) inner awareness, (v) feeling of heart beat, changes in blood flow and sound resonance, and (vi) recognition of linear, surface, three-dimensional and all pervasive awareness.

#### **4.2.1.1a Principles and basis of Cyclic Meditation**

Cyclic meditation is based on a concept that a combination of both ‘calming’ and ‘stimulating’ measures help in reaching a state of mental equilibrium. It is derived from a statement in Sage *Gauḍapāda’s Muṇḍūkā Upaniṣat Kārikā*:

लये सम्बोधयेत् चित्तं विक्षिप्तं शमयेत् पुनः ।

**सकषायं विजानीयात् समप्राप्तं न चालयेत् ॥३४४॥**

**Laye sambodhayet cittaà vikñiptaà śamayet punaù,**

***Sakaṣāyam vijñānīyāt samaprāptam na cālayet.***

*‘In a state of mental inactivity awaken the mind; when agitated, calm it; between these two states realize the possible abilities of the mind. If the mind has reached the state of perfect equilibrium then do not disturb it again’*

*(Muṇḍūkā Upaniṣat Kārikā: 3.44).*

For the most persons the mental states while doing routine activities (not necessarily associated with yoga) is neither ‘inactive’ nor ‘excited’, but is somewhere between these extremes and hence a combination of ‘awakening and calming’ measures may be better suited to reach a balanced, relaxed state. The foregoing idea

drawn from the traditional texts is the basis for this yoga practice called ‘*cyclic meditation*’.

Meditation is to gain mastery over the body and mind. The two main hurdles for gaining mastery over the mind are stupor (*laya*) and agitations (*vikṣipta*) of mind. This happens in all spiritual (*sādhana*) practices. The solution given by Sage *Gauḍapāda* is to address (*sambodhana*) the mind again and again when in stupor or oblivion, and slow down (*praśamana*) the mind when agitated. This important principle of practice is found intrinsically knit in all spiritual practices. In all meditation techniques this concept of focusing (activation) and defocusing (slowing down) is present in different proportions. However, to practice this one requires being constantly watchful and aware about changes occurring in the body and mind. Cyclic meditation helps to hone this skill (*kausāla*) as it consists the cycles of activating (*sambodhana*) and relaxing (*praśamana*) phases with unbroken (*taila dhāravat*) dispassionate (*niḥsaṅgaḥ*) awareness. The activation and relaxation is not alone meant at physical level, but of mind as well. The mind is alternately activated by focusing and confining (*deśa bandha*) on different changes occurring in body and mind; and relaxed by the process of defocusing (*ānantasamāpattibhyām*) with the attitude of witness. Thus cyclic meditation contains the intermittent cycles of *dhāraṇā* (pointed awareness) and *dhyāna* (pervasive awareness) finally stabilizing in the effortless expansive meditative state (*samatva*).

Sage *Gauḍapāda* further says that when the mind is awakened from the lethargy (*laya*) and is withdrawn from other objects, but is not established in equipoise and continues in an intermediate state, then *vijñānīyāt*, one should know; that mind to be *Sakaṣāyaṁ*, tinged with desire, in a state of latency. From that state too, it should be

diligently led to equipoise. When one practices this awakening (from *laya*) and calming (from *vikṣipta*) again and again the knots, blocks and latent desires in the subtle layers of mind (*kaṣāya*) surface and get released. This process of meditation helps to address all the unresolved patterns, issues, fears and phobias deep within the subconscious field. When mind settles in the state of balanced equipoise (*samaprāptam*), one must understand the possibilities of mind again getting distracted and hence should not move from that state. Sage *Gauḍapāda* further says in *Muṇḍūkā Upaniṣat Kārikā* that:

यदा न लियते चित्तं न च विक्षिप्यते पुनः । अनिङ्गनमनाभासं निष्पन्नं ब्रह्म तत्तदा ॥४६॥

*Yadā na liyate cittam na ca vikṣipyate punaḥ.*

*Aniṅganamanābhāsam niṣpannam brahma tattadā.*

‘When the mind is brought under control through the aforesaid process, does not become lost, in sleep; and also does not again, become dispersed amidst objects; and when the mind become motionless like a lamp in a windless place (*aniṅganama*); and does not get carried away by anything (*anābhāsam*); then it gets absorbed and becomes pure expansive Consciousness (*niṣpannam brahma*)’. (*Muṇḍūkā Upaniṣat Kārikā*: 3.46).

#### **4.2.1.1b Technique of Cyclic Meditation**

In the activating phase of cyclic meditation, the yoga postures are practiced about four times slower than that required by classical description. This slower practice requires more effort and subtle awareness than that required by the usual practice. The awareness is kept up throughout the practice with closed eyes, witnessing the changes

occurring in the body like, changes in respiratory rate, heart rate, blood flow and contraction and relaxation of muscles (Nagendra & Nagarathna, 2001). The postures and relaxation are practiced in such a way that it sets a slow cyclic rhythm in the body, *prāṇa* (vital energy) and the mind.

Being involved in specific practices keeps an overactive mind ‘busy’ and also stops one from falling asleep. For the best effects it is useful to (i) keep the eyes closed (ii) breathe slowly and rhythmically, and (iii) tune the awareness to the changes occurring in the body while doing slow and unhurried movements. During the practice of cyclic meditation the attention is enhanced by recognizing pointed awareness, linear awareness, surface awareness, three-dimensional-awareness and all pervasive awareness of body and mind. The practice of cyclic meditation is based on the principles described in the Patañjali yoga sutras (Taimini, 1961):

स्थिरसुखमासनम् ॥ *Sthirasukhamāsanam*. (PYS: 2.46)

प्रयत्नशैथिल्यानन्तसमापत्तिभ्याम् ॥ *Prayatnaśaithilyānantasamāpattibhyām*. (PYS: 2.47)

ततो द्वन्द्वानभिघातः ॥ *Tato dvandvānabighātaḥ*. (PYS: 2.48)

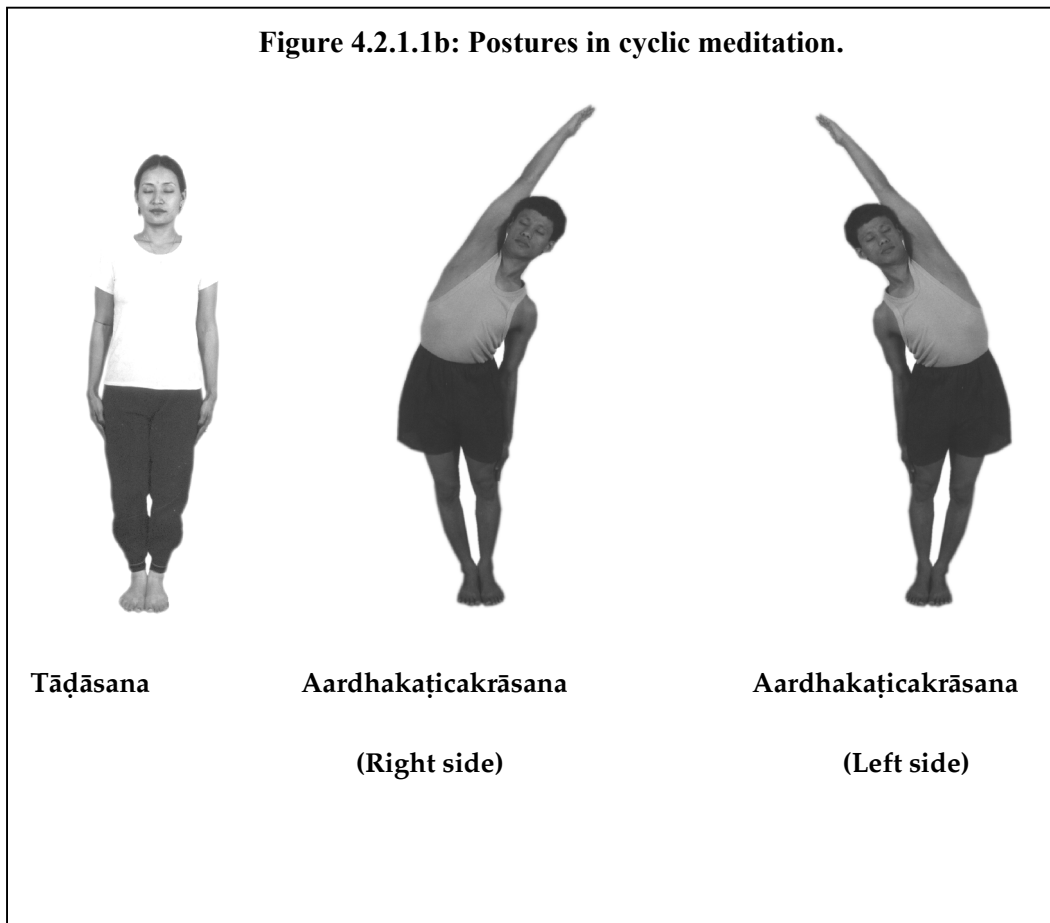
The postures are practiced slowly according to one’s physical capacity and comfort. The stability, effortlessness and mindfulness are emphasized while performing the body movements. In the final stage meditator is instructed to expand the awareness on infinite object like sky or ocean, and are encouraged to remain in that state effortlessly for longer duration. Thus though cyclic meditation is a moving technique, it consists of all the characteristic features of meditation (*dhyāna*): (i) single thought, (ii) effortlessness (*prayatnaśaithilyā*) (iii) mindfulness (*sāksī bhāva*) (iv)

slowness (*naidhānyā*), and (v) blissful expansiveness (*antasamāpatti*). The dual process of awareness and relaxation (stimulate – relax combination) not only releases the imbalances at body level but also at mental and emotional levels. The understanding of the subtleties of cyclic meditation by *Jñāna Yoga* brings about cognitional transformation to resolve the subtle intellectual conflicts. Therefore, cyclic meditation is considered as a holistic tool with other practices of the yoga powered by comprehensive knowledge base.

The relaxation techniques that are practiced in cyclic meditation are IRT (instant or isometric relaxation technique), QRT (quick relaxation technique) and DRT (deep relaxation technique). In IRT, the sudden isometric contraction of all muscles in the body is followed by brief relaxation while supine. The QRT is practiced in supine posture, where whole body is put in to rest while being aware of breathing process and the movement of abdomen and chest along with respiration. In DRT, the body is systematically relaxed part by part in supine position. Further the deep relaxation is provided and subtle awareness is maintained by chanting the syllables ‘A’, ‘U’, ‘M’ and ‘OM’ in sequential order. According to *Muṇḍūkā Upaniṣat* the syllables ‘A’ ‘U’ and ‘M’ constitute the primordial sound ‘OM’, which is at the base of all creations.

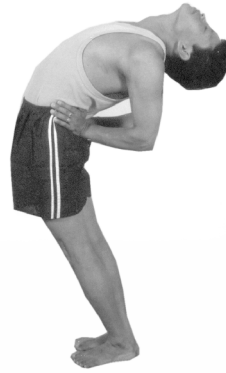
Depending upon the applied needs, different versions of cyclic meditation have been designed. The basic version consists four standing postures (*tādāsana*, *ardhakaṭīcakrāsana*, *pādahastāsana* and *ardhacakrāsana*) interspersed with IRT and DRT. The pictorial description of the postures in cyclic meditation is given figure 4.2.1.1b. In present study this basic version of cyclic meditation was investigated. In advanced version four standing and two sitting postures (*śaśāṅkāsana* and *ūṣṭrāsana*) are

interspersed with IRT (instant or isometric relaxation technique), QRT (quick relaxation technique) and DRT (deep relaxation technique).





**Pādahastāsana**



**Ardhamakrāsana**



**Supine posture for IRT, QRT and DRT**

#### **4.2.1.2 Sun salutation (*Surya Namaskara*)**

Sun salutation that includes a flow of 12 postures (Appendix-II) combined with breathing and chanting. These alternate forward and backward bending postures flex and stretch the spinal column and limbs through their maximum range (Nagendra, 2007).

#### **4.2.1.3 Breathing exercises**

Yogic breathing practices combined with simple body movements aimed to bring about a slow rhythmic breathing pattern which is the safest way to get mastery over the mind (Nagendra & Nagarathna, 2004). The principles involved in the technique of breathing were (i) slow down the rate of breathing while synchronizing the body

movements with breathing, (ii) ensure that exhalation was longer than inhalation and (iii) practice with full awareness of the touch of the flow of air through the nostril down the air passages.

#### **4.2.1.4 Lecture session**

They had lectures on physiology of menopause, healthy life style including diet, exercise, and yogic stress management techniques. Also, they were given yogic concepts to achieve a notional correction to help the participant (i) recognize her ability to tap the inner energy which is made of immense bliss that could keep up her youthful feeling and allay the fears, (ii) to restore her inbuilt freedom to change the responses to situations and (iii) learn to touch the bed of silence which is the source of all creativity that is essential for promotion of any cognitive function (Nagendra & Nagarathna, 2004).

#### **4.2.2 Control group intervention**

##### **4.2.2.1 Physical exercise**

The control group practiced a set of exercise program comprising of easy (non sweating) body movements supervised by physical trainers for the same duration of one hour daily, 5 days a week for 8 weeks. They also had lectures and individual counseling on conventional modern medical concepts about healthy life style including diet, exercise, and physiology of menopause and stress management techniques.

Appendices I and II show the detail of practices given to each group.

### **4.3 VARIABLES USED FOR ASSESSMENT**

#### **4.3.1 BIOCHEMICAL ASSESSMENT**

Serum FSH was used for initial screening of the subjects to satisfy one of the inclusion criteria. Blood samples for serum FSH levels were collected in Anand diagnostic laboratory, Bangalore on the 6<sup>th</sup> day of menstruation if she was menstruating regularly or at the time of recruitment itself if she had stopped menstruating or had irregular cycles. Estimation of FSH was carried out by Electrochemiluminescence method using Roche Elecsys 2010 FSH kit. As per the standardization, the normal range for the FSH values during follicular phase for regularly menstruating Indian women is 3.5 to 12.5mIU/ml (Anand laboratory FSH reference value). For the present study a value of >15 mIU/ml was considered as the inclusion criterion (Gordon & Speroff, 2002).

### **4.3.2 CLIMACTERIC SYMPTOM ASSESSMENT**

#### **4.3.2.1 Menopause Rating Scale**

#### **4.3.2.2 Greene Climacteric scale**

**4.3.2.1 Menopause Rating Scale (MRS)** – A rating scale of 11 items pertaining to menopausal symptoms were administered to the participants. The severity of the symptom ranged from 0 (mild) to 4 (very severe). The total score can therefore range from 0 (asymptomatic) to 44 (the highest severity of symptoms). Studies so far have established that the scale has good reliability and have all confirmed the existence of three dimensions of symptoms/complaints: psychological, somatic and urogenital. A good account of the history, reliability and validity of the MRS is available on the World Wide Web. For later reference and comparison we give here the factor structure that all these studies report:

Factor 1 (Psychological)	Items 4 – 7
Factor 2 (Somatic)	Items 1 – 3 and 11

The factors above are in decreasing order of the amount of variance explained by that factor. The total percentage of variance explained by these three factors is about 58.8 ([www.menopause-rating-scale.info](http://www.menopause-rating-scale.info)).

**4.3.2.2 Greene Climacteric scale (GCS)** - A checklist of 21 items pertaining to menopausal symptoms with severity scoring ranging from 0 - 3, (0 representing not at all, 1 a little bit, 2 quite a bit and 3 representing extremely bothersome symptom) was used to assess the climacteric symptoms for all participants. This scale was first devised by Greene in 1976 for the European population and later revised version of GCS in 1998 paper is used in this study (Greene, 1976; 1998).

The scale intends specifically to be a brief and standard measure of core climacteric symptoms or complaints to be used for comparative and replicative purposes across different types of studies whether they are medical, psychological, sociological or epidemiological in nature. The scale include measures of characteristics such as sexuality, clinical depression, quality of life and well being, or measures to assess some of the symptoms included in the scale in greater depth, such as vasomotor symptoms or insomnia. Finally, construct validity, including sensitivity of the scale described in the construction of this scale has been and is being established in a number of ongoing research studies (Alder, 1992; Alder et al, 1992; Derman et al, 1995; Ulrich et al, 1997).

Appendix – III shows GCS.

### **4.3.3 COGNITIVE ASSESSMENTS**

#### **4.3.3.1 Six-letter cancellation test**

#### **4.3.3.2 Punit Govil intelligence memory scale**

**4.3.3.1 Six-letter cancellation test (SLCT)** for adults is a paper pencil test that uses a letter cancellation task. Cancellation tests require visual selectivity and a repetitive motor response. This test was used to measure cognitive functions such as selective and focused attention, visual scanning as well as activation and inhibition of rapid responses. The normal value for Indian healthy adults for SLCT is  $38 \pm 6$  (Natu et al, 1997). A sample worksheet of six letter cancellation test is given in Appendix-V.

##### ***Testing procedure***

The six letter cancellation task consisted of a test worksheet which specified the six target letters to be cancelled and had a 'working section' which consisted of letters of the alphabet arranged randomly in 22 rows and 14 columns. The participants were asked to cancel as many of the six target letters as possible in the specified time, viz., 90 seconds. They were told that there were two possible strategies, i.e., (i) doing all six letters at a time or (ii) selectively any one target letter out of the six and were asked to choose whichever strategy suited them. They were also told that they could follow a horizontal, vertical or a random path according to their choice (Ritu et al, 2007). The scoring was done by a person who was unaware when the assessment was made, whether the participant was engaging in cyclic meditation or supine rest or control session and whether the assessment was 'before' or 'after' the session. The total number of cancellations and wrong cancellations were scored and the net scores were calculated by deducting wrong cancellations from the total cancellations attempted. As this test was administered before and after 8 weeks of intervention, to avoid any test-retest effect, parallel worksheets were prepared by changing the target

letters and the sequence of letters in the working section (Agarwal et al, 2002). There were different worksheets for the post assessments.

### ***Reliability and validity of the test***

Reliability refers to the consistency of measurement which is reflected in the reproducibility of the scores. The six letter cancellation test has been evaluated for its reliability and validity based on standard criteria. Reliability is ascertained based on (i) temporal stability and (ii) internal consistency (Singh, 2002). To assess temporal stability the correlation coefficient was calculated using the unpublished pilot data collected in twenty nine male healthy volunteers 'without any intervention'. The correlation was made for the data collected before and after twenty three minutes during which the subjects were given no specific intervention (Spearman's correlation coefficient). Participants read a book of their choice, while seated during the period. These subjects were different from those who were studied in cyclic meditation and supine rest sessions. The variable for which the correlation was made (i.e., the net score) demonstrated the temporal stability ( $r = 0.781$ ,  $P = 0.002$ ). Since the six letter cancellation test comprises one variable, internal consistency can not be calculated.

Validity concerns what the test measures and how well it does so. In the present study the six letter cancellation test is directly related to the attention of the person being examined. Hence it may be said that the content validity of this test is adequate for the purpose for which it is intended.

**4.3.3.2 Punit Govil intelligence memory scale (PGIMS)** is a battery of ten memory tests, which measures the remote memory, recent memory, mental balance, attention & concentration, delayed recall, immediate recall, retention for similar pairs, retention for dissimilar pairs, visual retention and recognition test. The participant is supposed to write the responses to the questions asked by the administrator. Out of ten, eight

tests are verbal; one test pertains to geometrical drawing and one on recognizing objects. The reliability of this scale has been tested and the norms for adults (>20 years) with no psychiatric / neurological illnesses are available. PGIMS is incorporated as one of the important tests to evaluate cognitive functions and organic brain dysfunctions (Pershad, 1994). Administration takes 15-20 minutes per participant.

Appendix VI (i to viii) shows the full PGIMS ten subtests

#### **4.3.4 PSYCHOLOGICAL ASSESSMENTS**

##### **4.3.4.1 Perceived Stress Scale**

##### **4.3.4.2 Eysenck's Personality Inventory**

**4.3.4.1 Perceived Stress Scale (PSS)** is a widely used psychological instrument for perception of stress. Items were designed to tap how unpredictable, uncontrollable and overloaded respondents find their lives. The scale also includes a number of direct queries about current levels of experienced stress. The PSS was designed for use in communities with at least junior high school education. It has 10 questions on about the feelings and thoughts during the last month. Validity is proved for higher PSS scores associated with greater vulnerability to stressful life event elicited depressive symptoms. Because levels of appraised stress should be influenced by daily hassles, major events and changes in coping resources, predictive validity of the PSS is expected to fall off rapidly after four to eight weeks (Cohen et al, 1993).

Appendix–VII shows PSS.

**4.3.4.2 Eysenck's Personality Inventory (EPI)** measures two major dimensions of personality, extroversion and neuroticism. The EPI items have been carefully

reworded so as to make them understandable to even the subjects of low intelligence / education. It is a 57-item dichotomous questionnaire rating the three psychological states: Neuroticism (24 items), Extroversion (24 items) and Lie scores (9 items). The scoring is accomplished by aligning the scoring keys furnished with the manual counting one for each underlined answer uncovered by the holes in the keys. The lie scale is used to eliminate subjects showing “desirability response set” i. e. to make the scale valid, reliable and useful in detecting individuals “faking good”. The ‘L’ score of 5 is set as the cutting point where inventory answers cease to be accepted. The retest reliability of the EPI runs between 0.84 and 0.94. N (neuroticism) factor is closely related to the inherited degree of lability of the autonomic nervous system, while the E (extroversion) factor is closely related to the degree of excitation and inhibition prevalent in the central nervous system. There is a significant trend for the N and E to decline with advancing age (Eysenck & Sybil, 1971).

Appendix-VIII shows EPI.

## **5. DATA EXTRACTION AND ANALYSIS**

### **5.1 Climacteric symptom scales**

#### **5.2 Cognitive variables**

#### **5.3 Psychological variables**

### **5.1 Climacteric symptom scales**

#### **5.1.1 Menopause Rating Scale**

The data were analyzed using SPSS 10. There have been indications that the three subscales of the MRS (measuring the psychological, somato-vegetative and urogenital dimensions) are not independent (Heinemann, 2004). Bearing this in mind, it was

decided to do a factor analysis with oblique rotation using the direct oblimin method, rather than an orthogonal rotation.

***Scoring:***

The score increases point by point with increasing severity of subjectively perceived complaints in each of the 11 items (severity expressed in 0 to 4 points in each item).

By checking one of the 5 possible boxes of "severity" for each of the items, the respondent provided her personal perception.

The total score of the MRS ranges between 0 (asymptomatic) and 44 (highest degree of complaints). The minimal/maximal scores vary between the three dimensions depending on the number of complaints allocated to the respective dimension of symptoms:

Psychological symptoms: 0 to 16 scoring points (4 symptoms: depressed, irritable, anxious, exhausted)

Somato-vegetative symptoms: 0 to 16 points (4 symptoms: sweating/flush, cardiac complaints, sleeping disorders, joint & muscle complaints)

Uro-genital symptoms: 0 to 12 points (3 symptoms: sexual problems, urinary complaints, vaginal dryness).

The composite scores for each of the dimensions (sub-scales) is based on adding up the scores of the items of the respective dimensions. The composite score (total score) is the sum of the dimension scores. Each item's response was recorded against respective participant's form number in the Microsoft excel sheet.

**5.1.2 Greene Climacteric Scale**

The purpose to use Greene Climacteric Scale (GCS) was to provide a brief but comprehensive and valid measure of climacteric symptomatology. The development of the GCS, a scale of 21 items, was motivated by the examination of seven separate

studies in which the number of items on the scale to assess the climacteric varied considerably (from 17 to 36). Greene (1976) initially conducted a factor analysis on a list of 30 symptoms reported by women aged 40-55 using a 30 item questionnaire in the United Kingdom. He identified three symptom clusters and labelled them as vasomotor, somatic and psychological. This was followed by an analysis on an Indian population by Indira and Murthy (1980) who also used the same 30 item questionnaire and found eight factors. Other studies (Hunter et al, 1986; Holte & Mikkelsen, 1991; Kaufert & Syrotuik, 1981; Mikkelsen & Holte, 1982; Abe et al, 1984) found between four and seven factors.

The Scale was originally constructed on the basis of a factor analysis of symptoms presented by a group of climacteric women attending a menopause clinic (Greene, 1976). It has subsequently been modified to take account of findings from five later factor analytic studies carried out by researchers in other countries using both general population and clinical samples (Greene, 1984, 1990). The wording of each symptom has also been standardised so reflect that most commonly used in each of these studies.

***Scoring:***

The Scale is designed for completion by the subject, but if desired or necessary, it could be used in the form of a structured interview. Each symptom is rated by the subject according to its severity using a four point rating scale. Such a rating method was used in the original factor analysis (Greene, 1976) and gives greater sensitivity to the measures than does a binary present/absent rating. Scores are assigned as follows:

Not at all = 0

A little = 1

Quite a bit = 2

Extremely = 3

The symptoms are related to psychological (anxiety and depression), somatic and vasomotor functions in the climacteric. Each response was filled against each participant's form number in the Microsoft excel sheet.

## **DATA ANALYSIS**

**MRS:** The factor analysis was done with oblique rotation using the direct oblimin method, rather than an orthogonal rotation. The usual strategy in doing factor analysis is to retain only those factors with eigenvalues larger than 1. The reason for this is that this criterion ensures that a factor accounts for at least as much variance as a single variable (Bennet, 1977). However, applying this criterion produced only two factors! Examination of the eigenvalues showed that the third largest eigenvalue was 0.985. Since this is not much less than unity, it was decided to extract three factors rather than apply the usual thumb rule.

**GCS:** Factor analysis the technique involves analyzing the intercorrelations among large numbers of symptoms in order to identify which symptoms cluster together to form groups or factors. This allows one to delineate the different facets of the symptom picture and to identify those symptoms which are an essential part of the syndrome and those which are not. The data was analyzed with the data reduction of responses of each participant for factor analysis in the SPSS version 10.0.

## **5.2 Cognitive variables**

### **5.2.1 Six-letter cancellation test**

The six letter cancellation task consisted of a test worksheet which specified the six target letters to be cancelled and had a 'working section' which consisted of letters of the alphabet arranged randomly in 22 rows and 14 columns. The participants were

asked to cancel as many of the six target letters as possible in the specified time, i.e., 1:30 minutes. They were told that there were two possible strategies, i.e., (i) doing all six letters at a time or (ii) selectively any one target letter out of the six and were asked to choose whichever strategy suited them. They were also told that they could follow a horizontal, vertical or a random path according to their choice (Natu & Agarwal, 1997). As this test was administered before and after the eight weeks of intervention, to avoid any test–retest effect, parallel worksheets were prepared by changing the target letters and the sequence of letters (Agarwal, Kalra, Natu, Dadich & Deswal, 2002).

***Scoring:***

The scoring was done by a person who was unaware when and on whom the assessments were made, whether the participant was engaging in yoga or control group and whether the assessment was ‘pre’ or ‘post’ of eight weeks intervention. The total number of cancellations and wrong cancellations were scored and the net scores were calculated by deducting wrong cancellations from the total cancellations attempted.

**DATA ANALYSIS**

The baseline data for SLCT was not normal as observed in Kolmogorov Smirnov test. Hence non parametric (Mann Whitney and Wilcoxon signed rank) tests were used to analyse the data. SPSS version 10.0 was used for analysis.

**5.2.2 Punit Govil Intelligence Memory Scale**

The participant is supposed to write the responses to the questions asked by the administrator. Out of ten, eight tests are verbal; one test pertains to geometrical drawing and one on recognizing objects. The reliability of this scale has been tested and the norms for adults (>20 years) with no psychiatric / neurological illnesses are

available. PGIMS is incorporated as one of the important tests to evaluate cognitive functions and organic brain dysfunctions (Pershad, 1994). Administration takes 15-20 minutes per participant.

***Scoring:***

**Subtests I & II:** 1 Score for each correct response, maximum total scores will be 6 and 5, respectively.

**Subtests III:** Alphabet and counting backward – 3 scores if all correct within 15 seconds, 2 if takes longer than 15 seconds, 1 if there is 1 mistake or omission, separately for alphabet and backward counting.

Counting backward by 3's – 3 scores if all correct within 30 seconds, 2 if takes longer than 30 seconds, 1 if there is 1 error or omission.

**Subtests IV:** Summation of digits forward and backward is the score for this subtest.

**Subtests V:** 1 score for each word correctly recalled (total 10).

**Subtests VI:** 1 Score for each clause correctly reproduced (maximum score 12).

**Subtests VII:** 1 Score for each correct reproduction of the associated word of the pair (total 5).

**Subtests VIII:** 1 Score each for the correctly reproduced pair, separately for each trial. Summation of scores on 3 trials is the final score (total 15).

**Subtests IX:** 1 Score for each type of geometrical figure correctly reproduced in sequence and number. Thus cards 1 to 3, 2 scores each, card 4, 3 scores and card 5, 4 scores (total 13).

**Subtests X:** Each object correctly recognized and named is to be given a score of 1 number of wrong identified objects are to be deducted from the earned score (total 10).

**DATA ANALYSIS**

The baseline data of 8 out of 10 PGIMS subtests was not normal as observed in Kolmogorov Smirnov test. Hence non parametric (Mann Whitney and Wilcoxon signed rank) tests were used for between group and within group analysis of data individually for all the ten subtests. SPSS version 10.0 was used for analysis.

### **5.3 Psychological variables**

#### **5.3.1 Perceived stress scale**

The PSS was designed for use in communities with at least junior high school education. It has 10 questions on about the feelings and thoughts during the last month. The participant was instructed to fill in the responses by ticking the option best suited to her depending on the last month experience of feeling stressful and coping with it.

Temporal Nature: Because levels of appraised stress should be influenced by daily hassles, major events and changing in coping resources, predictive validity is expected to fall off rapidly after four to eight weeks.

#### ***Scoring:***

PSS scores are obtained by reversing responses (i. e. 0=4, 1=3, 2=2, 3=1, 4=0) to the four positively stated items (Item 4<sup>th</sup>, 5<sup>th</sup>, 7<sup>th</sup> and 8<sup>th</sup>) and then summing across all scale items. A short four item scale can be made from questions 2, 4, 5 and 10 of the PSS 10 item scale.

#### **DATA ANALYSIS**

The data for PSS was normally distributed as observed in Kolmogorov Smirnov test, hence parametric (Independent sample's t test and Paired sample's t) tests were used

to analyze the between group and within group differences. The data were analyzed by SPSS version 10.0.

### **5.3.2 Eysenck's Personality Inventory**

The EPI items have been carefully reworded so as to make them understandable to even the subjects of low intelligence / education. It is a 57-item dichotomous questionnaire rating the three psychological states: Neuroticism (24 items), Extroversion (24 items) and Lie scores (9 items). The 'L' score of 5 is set as the cutting point where inventory answers cease to be accepted.

#### ***Scoring:***

The scoring is accomplished by aligning the scoring keys furnished with the manual counting one for each underlined answer uncovered by the holes in the keys. EPI can also be scored computerized, a scoring program written in FORTRAN prepared by Alan Hendrickson which is included in the manual.

### **DATA ANALYSIS**

The data for EPI (Extroversion and Neuroticism) was normally distributed as observed in Kolmogorov Smirnov test, hence parametric (Independent sample's t test and Paired sample's t) tests were used to analyze the between group and within group differences. The data were analyzed by SPSS version 10.0.

## **6. RESULTS**

### **6.1 Climacteric symptom assessments**

#### **6.1.1 Factor analysis of Menopause Rating Scale**

#### **6.1.2 Factor analysis of Greene Climacteric Scale**

### **6.2 Cognitive variables**

#### **6.2.1 Six-letter cancellation test**

#### **6.2.2 Punit Govil Intelligence Memory Scale**

## **6.3 Psychological variables**

### **6.3.1 Perceived stress scale**

### **6.3.2 Eysenck's Personality Inventory**

## **6.1 Climacteric symptom assessments**

### **RESULTS OF STUDY 1 - Cohort study**

This cohort study comprised 518 Indian women who satisfied the inclusion criteria of age between 45-55 years. The study aimed at exploring the factor structure of the 11 item Menopause Rating Scale and 21 item Greene Climacteric Scale in Indian women. This was part of a larger study whose aim was to aid menopausal women alleviate their symptoms.

### 6.1.1 Factor analysis of Menopause Rating Scale for validation in Indian population

Table 1 shows the demographic data. The mean age of the subjects was  $48.03 \pm 3.40$ .

**Table 1**  
**Demographic data**

<i>Category</i>		<b>Number</b>
Participants between ages 46-50 (years)		334
Participants between ages 51-55 (years)		184
Housewives		295
Working women	Bankers	96
	Teachers	82
	Self-employed	45
The average age was $48.03 \pm 3.40$		

Three factors accounting for 59.1% of the total variance were extracted. The resulting factor structure differs from the one seen for populations in the west in that item 3 (sleep problems) is associated with the psychological factor rather than the somatic factor. In addition, the urogenital factor accounts for slightly more variance than the somatic factor in our population. The items corresponding to the three factors are shown in Table 2 along with the percentage of variance explained by each factor.

**Table 2**

<b>Factor</b>	<b>Items</b>	<b>% of variance explained</b>
1 (Psychological)	3 – 7	40.3
2 (Urogenital)	8 – 10	9.9
3 (Somatic)	1, 2 and 11	9

The factor loadings of the individual factors are given in Table 3. The Kaiser-Meyer-Olkin statistic, a measure of sampling adequacy, had a value of 0.879 indicating that the pattern of correlations is adequate for a factor analysis. Bartlett's test for sphericity of the data is highly significant ( $p < 0.001$ ) and so a factor analysis is appropriate (Field, 2000).

**Table 3**

	<b>Factor 1</b>	<b>Factor 2</b>	<b>Factor 3</b>	
<b>Q1</b>			.809	
<b>Q2</b>			.699	
<b>Q3</b>	.411			
<b>Q4</b>	.748			
<b>Q5</b>	.836			
<b>Q6</b>	.900			
<b>Q7</b>	.691			
<b>Q8</b>		.638		
<b>Q9</b>		.715		
<b>Q10</b>		.834		
<b>Q11</b>			.558	

The component correlation matrix showing the correlation between the factors is displayed in Table 4. The correlations are all significant at the 0.01 level of significance indicating as anticipated, that the subscales are not fully independent. Assessing the reliability of the data gave a Cronbach's alpha of 0.846. The value of Cronbach's alpha for the scores in the three domains was 0.694.

**Table 4. The component correlation matrix**

	<b>Psychological</b>	<b>Urogenital</b>	<b>Somatic</b>
<b>Psychological</b>	1	0.433	0.464

<b>Urogenital</b>		1	0.318
<b>Somatic</b>			1

All correlations are significant at the 0.01 level

Table 5 shows the means and standard deviations of the scores of the three factors for our sample.

**Table 5. Means and standard deviations**

<b>Factor</b>	<b>Mean ± SD</b>
<b>Psychological</b>	5.59 ± 4.14
<b>Urogenital</b>	1.78 ± 2.1
<b>Somatic</b>	2.96 ± 2.30
<b>Total score</b>	10.34 ± 7.07

### **6.1.2 Factor analysis of Greene Climacteric Scale for validation in Indian population**

Four factors accounting for 53.6% of the variance were extracted. However, the pattern matrix for the factors contained only three factors after the criterion of factor loadings greater than 0.4 was applied. The resulting factor structure accounts for 48.6% of the total variance and is identical to the factor structure proposed by Greene except that item 1 (“Heart beating quickly or strongly”) does not contribute to any of the factors. The items contributing to the three factors are:

Factor 1 (Psychological): Items 2 – 11

Factor 2 (Somatic): Items 12 – 18

Factor 3 (Vasomotor): Items 19 – 21

Item 1, which does not appear in these three factors had factor loadings of only 0.27 and 0.26 on factors 2 and 3 respectively. By any reasonable criterion therefore, this item may be neglected. The factor loadings of the individual items on the three factors are given in Table 6.

**Table 6. Factor Loadings using the Direct Oblimin method (Pattern Matrix)**

<b>Item</b>	<b>Factor 1</b>	<b>Factor 2</b>	<b>Factor 3</b>
<b>Q2</b>	0.588		
<b>Q3</b>	0.424		
<b>Q4</b>	0.531		
<b>Q5</b>	0.646		
<b>Q6</b>	0.647		
<b>Q7</b>	0.526		
<b>Q8</b>	0.697		
<b>Q9</b>	0.768		
<b>Q10</b>	0.692		
<b>Q11</b>	0.672		
<b>Q12</b>		0.513	
<b>Q13</b>		0.517	
<b>Q14</b>		0.703	
<b>Q15</b>		0.464	
<b>Q16</b>		0.579	
<b>Q17</b>		0.811	
<b>Q18</b>		0.553	
<b>Q19</b>			0.868
<b>Q20</b>			0.865
<b>Q21</b>			0.493

Climacteric research has long suffered from the lack of a standard instrument to measure the range of symptoms most commonly experienced by women at that time of their lives. It is a long recognized problem, highlighted by Jaszmann (1984) at the Fourth and by Utian (1990) at the Sixth International Congress on the Menopause. In the absence of a standard instrument, individual researchers have tended to draw up their own adhoc measures. These usually consist of lists of ‘menopausal’ symptoms, subjectively selected, arbitrarily classified and rated merely present or absent, the resulting measure being poorly scaled and of unknown psychometric properties. The oft cited and seminal study by Neugarten and Kraines (1965) of ‘menopausal symptoms in women of various ages’, published over 30 years ago, is an early example of this practice—a practice which still persists even in more recent times (Bungay et al 1980; Koster & Davidsen, 1993). Alternatively, others have relied on the use of existing standard scales. While, in the context of the research objectives,

such scales may be quite appropriate, they must be used with care since they have been designed for use with other types of populations, such as psychiatric patients. In this respect the Hamilton Rating Scales of Clinical Anxiety and Depression (Dennerstein et al, 1979; Channon & Ballanger, 1986) and the Beck Depression Index (Campbell & Whitehead, 1977; Schneider et al, 1977) have proved to be the most widely used. Another popular measure is the General Health Questionnaire (Campbell & Whitehead, 1977; Schneider et al, 1977) an instrument designed to measure psychiatric morbidity in general population samples.

The only 'menopause specific' symptom measure until 1976 was the Blatt /Kupperman Index, which because of its inadequate psychometric properties and archaic wording, had been seriously discredited (Alder, 1998). The major criticism of this scale is that the summation of diverse symptoms to yield a total 'menopause' symptoms index is without meaning.

At this point it is appropriate to distinguish between the terms climacteric and menopause. Climacteric refers to a transitional phase in the life span during which a woman gradually moves from being reproductive to nonreproductive. Along with biological, it also has social and psychological implications (Greene, 1984). The menopause, the final cessation of menses, is a more circumscribed event occurring within the longer climacteric phase and is a sign that a particular biological point has been reached in the transitional climacteric process. The climacteric being a multifaceted phenomenon, it follows that symptoms occurring during that time may come from different domains, have differing aetiologies and should consequently be categorised and measured separately from each other and not totaled to yield a single score as they are in the Blatt/Kupperman Index.

Defining 'factor' – In a big set of variables, when some variables have some traits / features in common, a 'factor' is said to exist (Field, 2000).

Factor analysis is a mathematical technique to delineate those symptoms thought to constitute the syndrome or condition. Factor analysis is a multi-variant mathematical technique traditionally used in psychometrics to construct measures of psychological characteristics such as intellectual and personality traits. Later, it was adapted by clinical psychologists and psychiatrists to develop scales to measure conditions, such as anxiety and depression, which present with multiple and varied symptomatology. In this context the technique involves analyzing the intercorrelations among large numbers of symptoms in order to identify which symptoms cluster together to form groups or factors. This allows one to delineate the different facets of the symptom picture and to identify those symptoms which are an essential part of the syndrome and those which are not. The relationship between a symptom and a factor is measured by a correlation co-efficient, known as a factor loading.

The first factor analytic study of symptoms presented by women during the climacteric was carried out by Greene (1976), for the purpose of constructing a comprehensive measure of the multi-faceted and wide ranging symptom picture presented by climacteric women. The resulting scale consisted of three separate subscales measuring vasomotor, somatic and psychological complaints. This study was quickly followed by six other similar factor analytic studies of similar types of symptoms (Indira & Murthy, 1980; Kaufert & Syrotuik, 1981; Mikkelsen & Holte, 1982; Abe et al, 1984; Hunter et al, 1986; Holte & Mikkelsen, 1991).

The general consensus, therefore, seems to be that climacteric symptoms fall into three major independent groups. It should be noted that a common three factor structure emerges regardless of whether the sample is from a clinical or general

population. The logic of factor analysis is that each of these three facets of the climacteric syndrome is conceptually distinct, each may have its own separate aetiology and therefore each should be measured independently. This results in the generation of a symptom profile for each subject.

Factor analysis is of two types:

- 1) Exploratory factor analysis - To explore the structure in a set of interrelated variables
- 2) Confirmatory factor analysis confirm the factor structure discovered earlier

The Kaiser-Meyer-Olkin (KMO) statistic, a measure of sampling adequacy, had a value of 0.918, indicating that the pattern of correlations is adequate for a factor analysis. It is also essential for a factor analysis that there be some relationships between the variables and so the sphericity of the data needs to be checked. Bartlett's test for sphericity for the data is highly significant ( $p < 0.001$ ) and so a factor analysis is appropriate (Field, 2000). The component correlation matrix which shows the correlations between the factors is displayed in Table 7. The correlations are all significant at the 0.01 level of significance, justifying the need for an oblique rotation rather than an orthogonal rotation. Reliability of the data was also assessed. The split-half reliability was 0.83 and Cronbach's alpha was 0.91.

**Table 7. The Component Correlation Matrix  
(Oblique rotation)**

	<b>Psychological</b>	<b>Somatic</b>	<b>Vasomotor</b>
<b>Psychological</b>	1	0.48	0.41

<b>Somatic</b>		1	0.36
<b>Vasomotor</b>			1

The correlations are all significant at the 0.01 level.

Table 8 shows the means and the standard deviations of each sub-scale for the three factors of the oblique rotation. The table also shows the correlations between the sub-scales and the factor scores. The means for our study are much lower than the means given by Greene (1976).

**Table 8. Means, Standard deviations and Correlations**

<b>Factors</b>	<b>Mean</b>	<b>SD</b>	<b>Correlation*</b>
<b>Psychological</b>	8.12	5.87	0.983
<b>Somatic</b>	4.64	3.73	0.975
<b>Vasomotor</b>	2.39	2.10	0.960

\*The correlation is between the sub-scales and the original factor scores

This comparison and another comparison with an Ecuadorian population are displayed in Table 9.

**Table 9. Comparison of means for three studies**

<b>Factors</b>	<b>Indian women</b>	<b>Sierra <i>et al</i> (2005)</b>	<b>Greene (1976)*</b>
<b>Psychological</b>	8.28 ± 5.87	8.84 ± 4.67	19.62 ± 9.69
<b>Somatic</b>	4.64 ± 3.73	4.5 ± 2.74	7.18 ± 4.57
<b>Vasomotor</b>	2.39 ± 2.10	3.82 ± 1.9 <sup>†</sup>	6.46 ± 2.79
<b>Total</b>	15.15 ± 10.01	17.16 ± 8.45	33.26**

\*Note: The means quoted for Greene are for the three scales in Greene's 1976 study.

\*\*It is not possible to give the standard deviation using the data as given by Greene

<sup>†</sup> The standard deviation of 1.9 is an estimate, since they have given the data for item 21 separately. The mean of 3.82 is correct.

Indira has previously conducted a similar study on a sample of 105 Indian women in 1980. They used the original 30 item questionnaire of Greene and extracted eight factors with eigenvalues greater than one. Of these, the first three are the ones

obtained by Greene. The method of factor extraction used by Indira was varimax rotation.

Since the varimax method assumes no relationship between the distinct factors to be extracted, it was also of interest to us to examine this hypothesis and therefore to also use orthogonal (varimax) rotation instead of oblique. The resulting analysis yielded four distinct factors and showed that Greene’s psychological factor (items 1 – 11) splits naturally into two distinct factors which can be identified as anxiety (items 1 – 5 and 18) and depression (items 2 and 6 – 11). These four factors together account for 53.6% of the total variance. Our analysis also showed that item 2 (“Feeling tense or nervous”) loads on both factors 1 (depression) and 3 (anxiety). Table 10 gives the factor loadings for varimax rotation.

**Table 10. (Factor Loadings using the Varimax method)**

	<b>Factor 1</b>	<b>Factor 2</b>	<b>Factor 3</b>	<b>Factor 4</b>
<b>Q1</b>			0.567	
<b>Q2</b>	0.471		0.543	
<b>Q3</b>			0.529	

Q4			0.601	
Q5			0.600	
Q6	0.550			
Q7	0.637			
Q8	0.665			
Q9	0.711			
Q10	0.608			
Q11	0.664			
Q12		0.469		
Q13		0.521		
Q14		0.661		
Q15		0.496		
Q16		0.644		
Q17		0.740		
Q18			0.495	
Q19				0.823
Q20				0.814
Q21				0.477

**RESULTS OF STUDY 2 - Randomised control trial to evaluate the efficacy of IAYT in climacteric syndrome**

The flowchart below describes the trial profile. Out of 120 participants, there were 12 dropouts, 5 in yoga and 7 in the control group due to inability to come to the venue regularly (attendance >75% considered regular) because of (i) husband's ill health, (ii) transfer to other cities and (iii) unexpected events in the family.

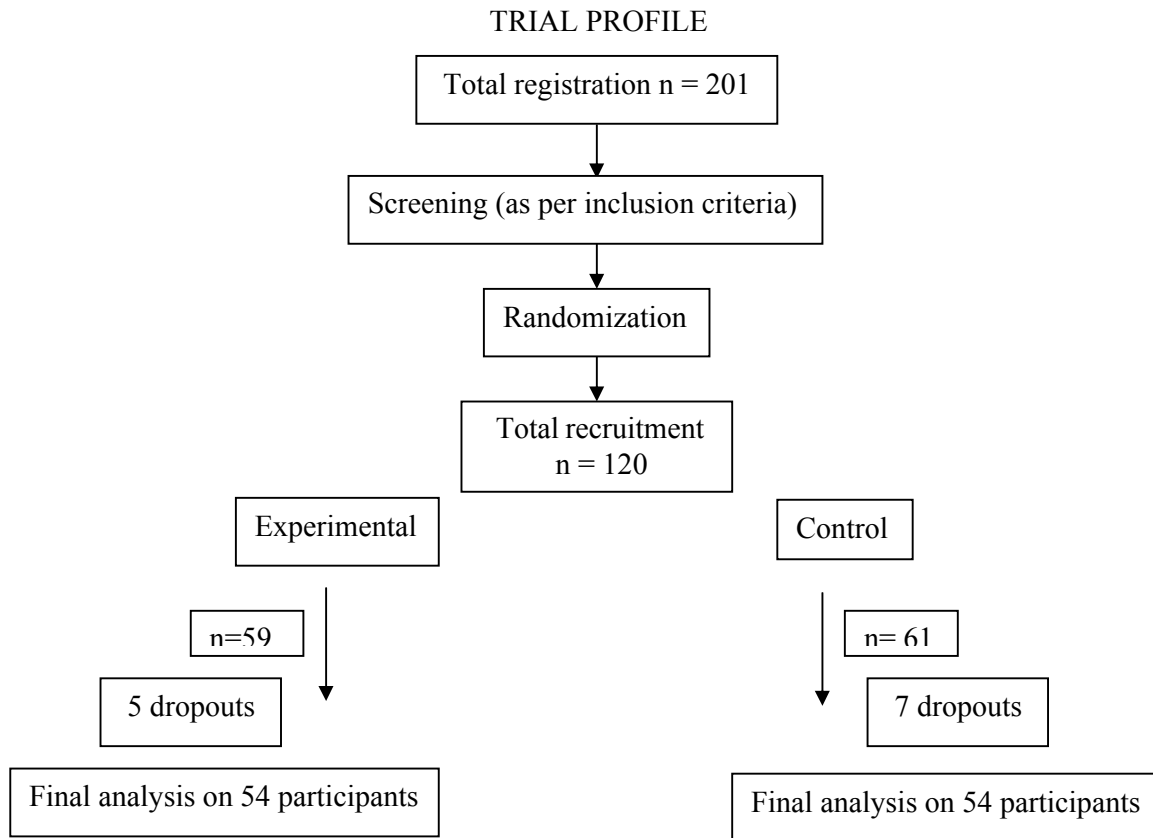


Table 11 shows demographic data. Maximum participation was from age group 46-50 years. Out of the total participants, 87.76% were housewives and working class were either high school teachers or bank officials.

**TABLE – 11 Demographic data**

S no.	Variables	YOGA		CONTROL	
1.	Age (mean $\pm$ SD)	49 $\pm$ 3.6		48 $\pm$ 4	
	Number between 40-45 (years)	13		14	
	Number between 46-50 (years)	22		23	
	Number between 51-55 (years)	19		17	
2.	W / H	14 / 40		9 / 45	
3.	BMI (mean $\pm$ SD)	28 $\pm$ 3.4		29 $\pm$ 4	
4.	V / NV	43 / 11		45 / 9	
5.	A – Premenopausal	no.	FSH (mean $\pm$ SD) mIU/ml	no.	FSH (mean $\pm$ SD) mIU/ml
		14	43.88 $\pm$ 21.64	16	37.94 $\pm$ 17.52
	B – Irregular menstruation	17	47.16 $\pm$ 23.45	20	38.72 $\pm$ 14.94
	C – Menopausal	9	83.65 $\pm$ 43.59	7	56.9 $\pm$ 20.77
	D – Postmenopausal	14	59.5 $\pm$ 18.67	11	66.81 $\pm$ 21.14
6.	FSH (mIU/ml) mean $\pm$ SD	56 $\pm$ 29.9		47 $\pm$ 21.5	

Note: W / H – Working / Housewives; V / NV – Vegetarian / Non vegetarian; A – Women having regular menstruation, B - Irregular menstrual cycles, C - Menopause attained between 1 year and 3 years ago, D - Menopause attained more than 3 years ago.

Foot note: There is no significant difference between groups in all the variables at baseline.

At base line the data were not significantly different between the two groups for FSH (follicle stimulating hormone) and BMI (body mass index) ( $p = 0.11$ ,  $p = 0.07$  respectively - Mann Whitney test).

## 6.2 Cognitive variables

### 6.2.1 Six-letter cancellation test

The data at baseline for SLCT ( $p = 0.528$ ) were not significantly different between the two groups.

SLCT: The values of SLCT improved in both groups. Mann Whitney test showed significantly greater improvement ( $p < 0.001$ ) in yoga group (effect size 1.16) than the control (effect size 0.6).

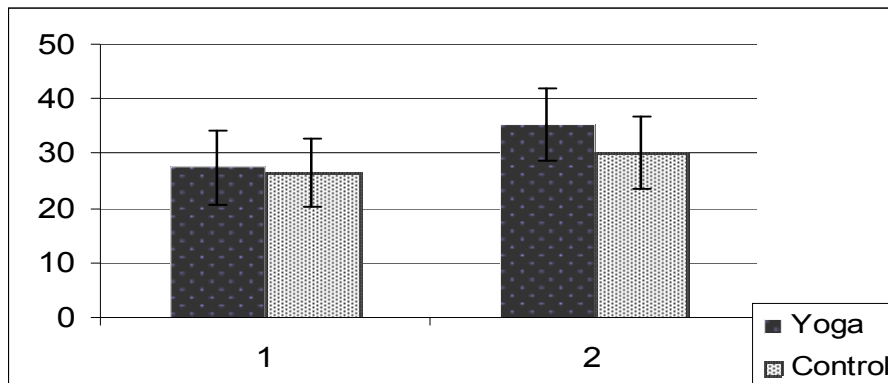
**Table 12** shows the results of Six-letter cancellation test (SLCT):

Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group $\wedge$ P	Effect size Pre-post	Between Y-C $\square$ P	Effect size Y-C	Normative data
Yoga	27.43 $\pm$ 6.91	35.31 $\pm$ 6.72	< 0.001	1.16	< 0.001	0.8	30 $\pm$ 6
Control	26.48 $\pm$ 6.37	30.19 $\pm$ 6.63	< 0.001	0.6			

Note: Mean  $\pm$  standard deviation and P values are calculated for SLCT using  $\wedge$ Wilcoxon p value;  $\square$ Mann Whitney p value.

Foot note: There was greater improvement in yoga than the control group in SLCT

### Six-letter cancellation test (SLCT)



### 6.2.2 Punit Govil Intelligence Memory Scale

All the subtests of PGIMS were not significantly different between the two groups (p value for Test I = 0.39, II = 0.49, III = 0.24, IV(i) = 0.43, IV(ii) = 0.01, V = 0.625, VI = 0.59, VII = 0.72, VIII = 0.98, IX = 0.92, X = 0.06).

The results for all PGIMS tests (Table 13 to 23) are reported as follows:

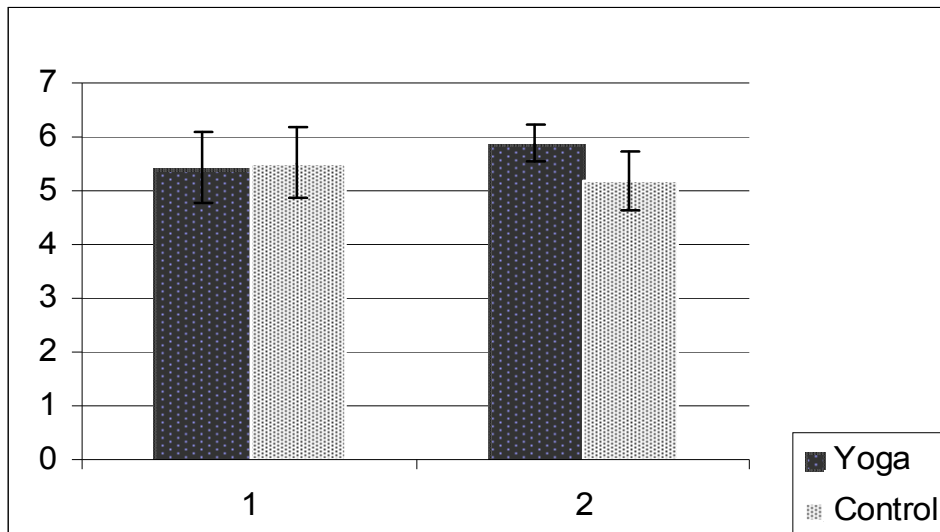
PGIMS-I (Remote memory) – Both groups showed significant increase (p = 0.001, Wilcoxon test). There was greater improvement (p < 0.001, Mann Whitney) in yoga (effect size 0.84) than the control group (effect size 0.58).

**TABLE-13: Results of Punit Govil Intelligence Memory Scale (PGIMS-I) showing the mean ± SD in pre and post data of yoga and control group**

Groups	Pre Mean ± SD	Post Mean ± SD	Within group ^p	Effect size Pre-post	Y-C □p	Effect size Y-C	Normative data
<b>Yoga</b>	5.43 ± 0.66	5.87 ± 0.34	<0.001	0.84	<0.001	1.55	5.78 ± 0.52
<b>Control</b>	5.52 ± 0.67	5.17 ± 0.54	0.001	0.58			

\* p<0.001, Pre v/s Post data of yoga and control group

**PGIMS - I**



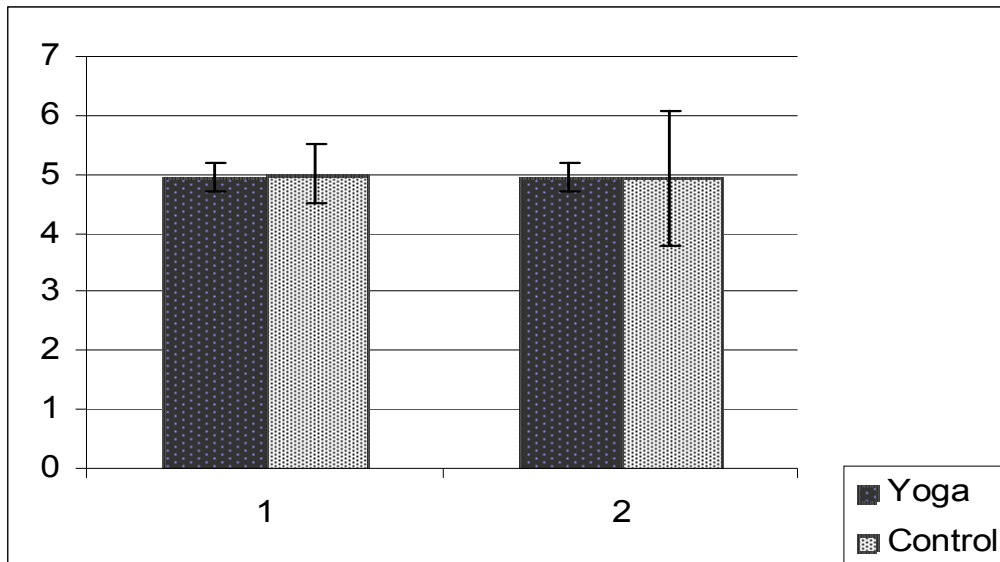
PGIMS-II (Recent memory) – There was no change observed in this test, since the effect sizes were very low (0.01, Mann Whitney) in both groups.

**TABLE-14: Results of Punit Govil Intelligence Memory Scale (PGIMS-II) showing the mean  $\pm$  SD in pre and post data of yoga and control group**

Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group ^p	Effect size Pre-post	Y-C $\square$ p	Effect size Y-C	Normative data
Yoga	4.94 $\pm$ 0.23	4.94 $\pm$ 0.23	0.83	0.00	0.08	0.01	4.91 $\pm$ 0.29
Control	5 $\pm$ 0.51	4.93 $\pm$ 1.15	0.439	0.08			

\* p<0.001, Pre v/s Post data of yoga and control group

**PGIMS - II**



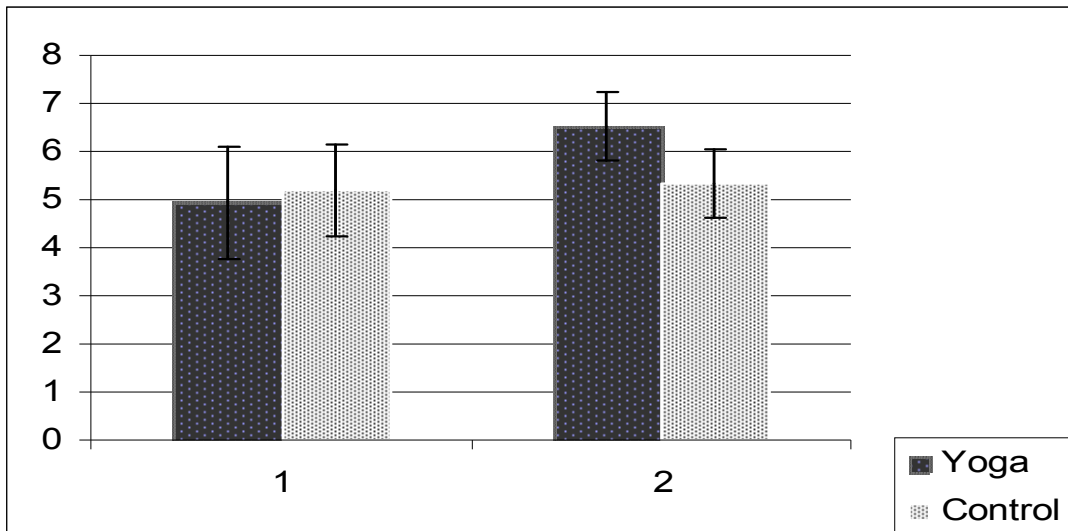
PGIMS-III (Mental balance) – Yoga group showed significant increase (p < 0.001, Wilcoxon test) whereas the control group showed no change (p = 0.39). There was greater improvement (p < 0.001, Mann Whitney) in yoga group (effect size 1.66) than the control group (effect size 0.17).

**TABLE-15: Results of Punit Govil Intelligence Memory Scale (PGIMS-III) showing the mean  $\pm$  SD in pre and post data of yoga and control group**

Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group ^p	Effect size Pre-post	Y-C $\square$ p	Effect size Y-C	Normative data
Yoga	4.93 $\pm$ 1.15	6.52 $\pm$ 0.72	<0.001	1.66	0.08	0.01	4.91 $\pm$ 0.29
Control	5.19 $\pm$ 0.93	5.33 $\pm$ 0.7	0.394	0.17			

\* p<0.001, Pre v/s Post data of yoga and control group

**PGIMS - III**



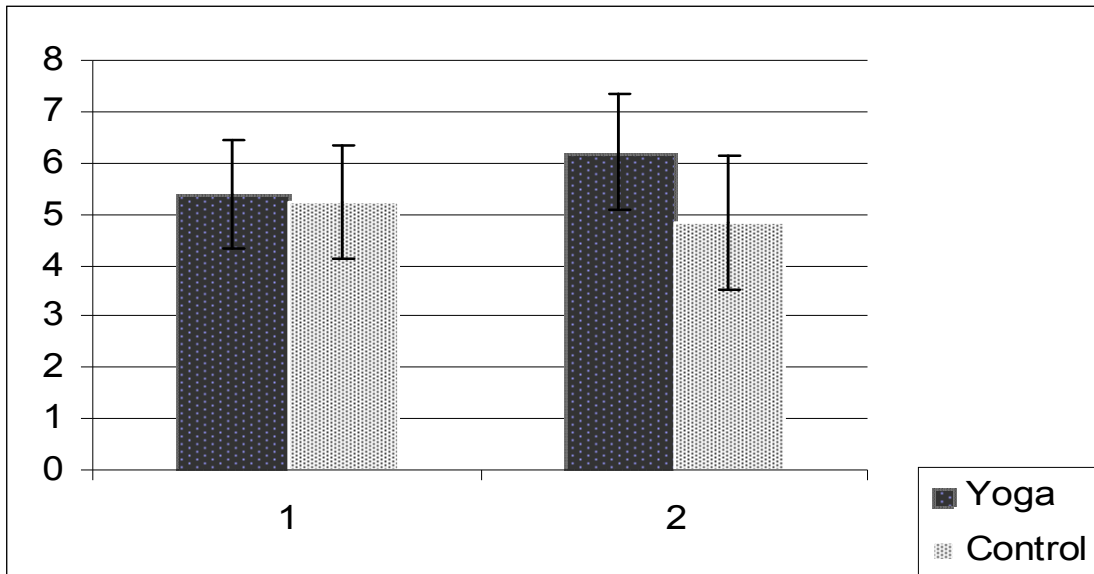
PGIMS-IV (i) (Attention & Concentration) – Both groups showed significant increase with greater improvement (p < 0.001, Mann Whitney) in yoga (effect size 0.74) than the control group (effect size 0.34).

**TABLE-16 (i): Results of Punit Govil Intelligence Memory Scale (PGIMS-IV-I) showing the mean  $\pm$  SD in pre and post data of yoga and control group**

Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group ^p	Effect size Pre-post	Y-C $\square$ p	Effect size Y-C	Normative data
Yoga	5.39 $\pm$ 1.04	6.2 $\pm$ 1.14	<0.001	0.74	<0.001	0.94	**8.46 $\pm$ 1.91
Control	5.24 $\pm$ 1.11	4.83 $\pm$ 1.3	0.014	0.34			

\* p<0.001, Pre v/s Post data of yoga and control group

**PGIMS – IV (i)**



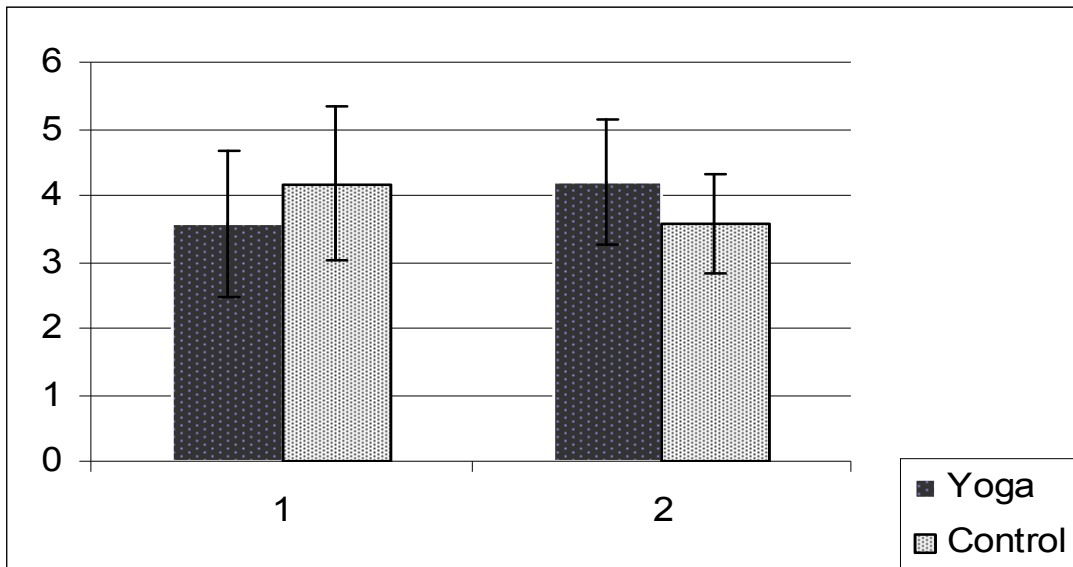
PGIMS-IV (ii) (Attention and concentration) – Both groups showed significant increase ( $p = 0.001$ , Wilcoxon test). There was similar trend of improvement ( $p < 0.001$ , Mann Whitney) in yoga (effect size 0.61) and the control group (effect size 0.63).

**TABLE-16 (ii): Results of Punit Govil Intelligence Memory Scale (PGIMS-IV-II) showing the mean  $\pm$  SD in pre and post data of yoga and control group**

Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group ^p	Effect size Pre-post	Y-C $\square$ p	Effect size Y-C	Normative data
<b>Yoga</b>	3.57 $\pm$ 1.09	4.19 $\pm$ 0.95	<0.001	0.61	<0.001	0.58	**8.46 $\pm$ 1.91
<b>Control</b>	4.17 $\pm$ 1.15	3.56 $\pm$ 0.74	0.001	0.63			

\*  $p < 0.001$ , Pre v/s Post data of yoga and control group

**PGIMS – IV (ii)**



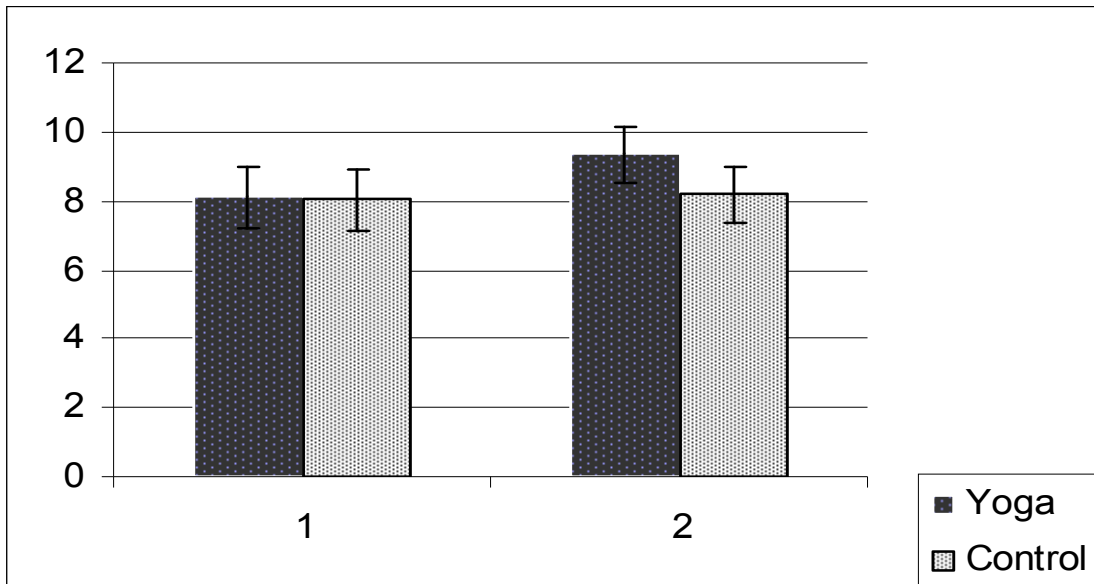
PGIMS-V (Delayed recall) – The yoga group showed significant increase ( $p < 0.001$ , Wilcoxon test) whereas the control group showed no improvement ( $p = 0.36$ ). There was greater improvement ( $p < 0.001$ , Mann Whitney) in yoga (effect size 1.47) than the control group (effect size 0.18).

**TABLE-17: Results of Punit Govil Intelligence Memory Scale (PGIMS-V) showing the mean  $\pm$  SD in pre and post data of yoga and control group**

Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group $\wedge$ p	Effect size Pre-post	Y-C $\square$ p	Effect size Y-C	Normative data
<b>Yoga</b>	8.11 $\pm$ 0.88	9.33 $\pm$ 0.78	<0.001	1.47	<0.001	1.20	6.99 $\pm$ 1.53
<b>Control</b>	8.02 $\pm$ 0.9	8.17 $\pm$ 0.8	0.363	0.18			

\*  $p < 0.001$ , Pre v/s Post data of yoga and control group

**PGIMS - V**



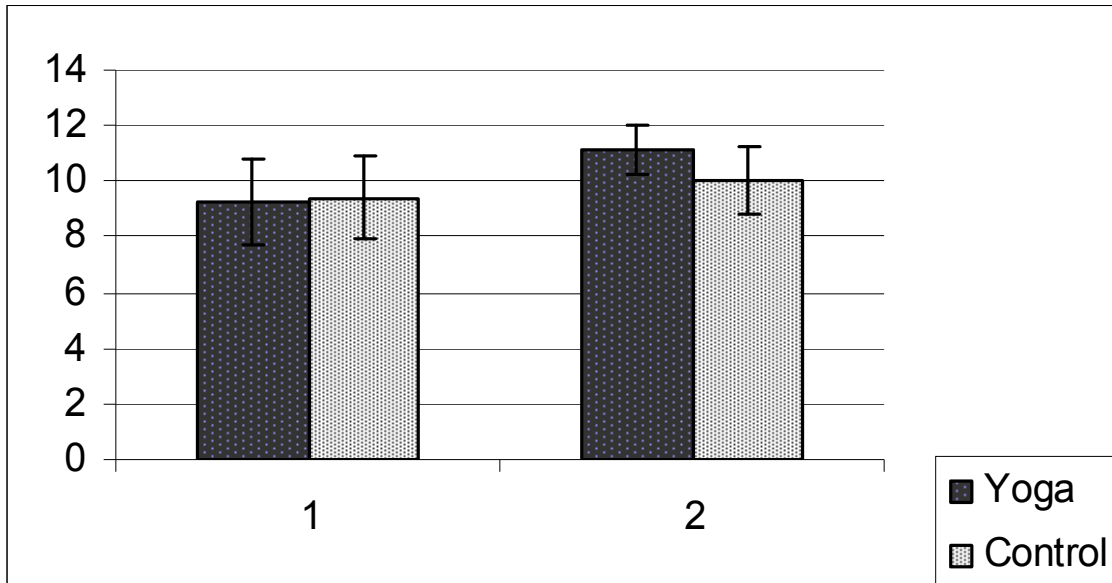
PGIMS-VI (Immediate recall) – The yoga group showed significant increase ( $p < 0.001$ , Wilcoxon test) but the control group showed no significant change ( $p = 0.015$ ). There was greater improvement ( $p < 0.001$ , Mann Whitney) in yoga (effect size 1.51) than the control group (effect size 0.42).

**TABLE-18: Results of Punit Govil Intelligence Memory Scale (PGIMS-VI) showing the mean  $\pm$  SD in pre and post data of yoga and control group**

Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group ^p	Effect size Pre-post	Y-C $\square$ p	Effect size Y-C	Normative data
Yoga	9.26 $\pm$ 1.51	11.13 $\pm$ 0.89	<0.001	1.51	<0.001	0.93	7.41 $\pm$ 1.98
Control	9.41 $\pm$ 1.5	9.98 $\pm$ 1.21	0.015	0.42			

\*  $p < 0.001$ , Pre v/s Post data of yoga and control group

**PGIMS - VI**



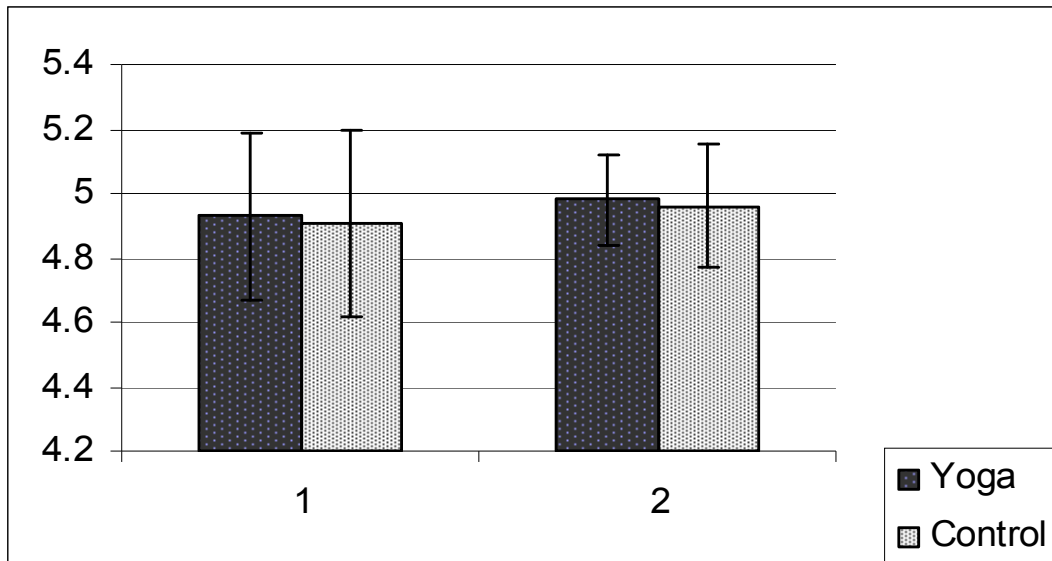
PGIMS-VII (Verbal retention of similar pairs) – There was no change in both the groups ( $p = 0.18$  in yoga,  $p = 0.25$  in control group in Wilcoxon test). There was no difference between the groups ( $p=0.56$ , Mann Whitney).

**TABLE-19: Results of Punit Govil Intelligence Memory Scale (PGIMS-VII) showing the mean  $\pm$  SD in pre and post data of yoga and control group**

Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group $\wedge p$	Effect size Pre-post	Y-C $\square p$	Effect size Y-C	Normative data
Yoga	4.93 $\pm$ 0.26	4.98 $\pm$ 0.14	0.18	0.24	0.56	0.10	4.36 $\pm$ 0.78
Control	4.91 $\pm$ 0.29	4.96 $\pm$ 0.19	0.257	0.20			

\*  $p < 0.001$ , Pre v/s Post data of yoga and control group

**PGIMS - VII**



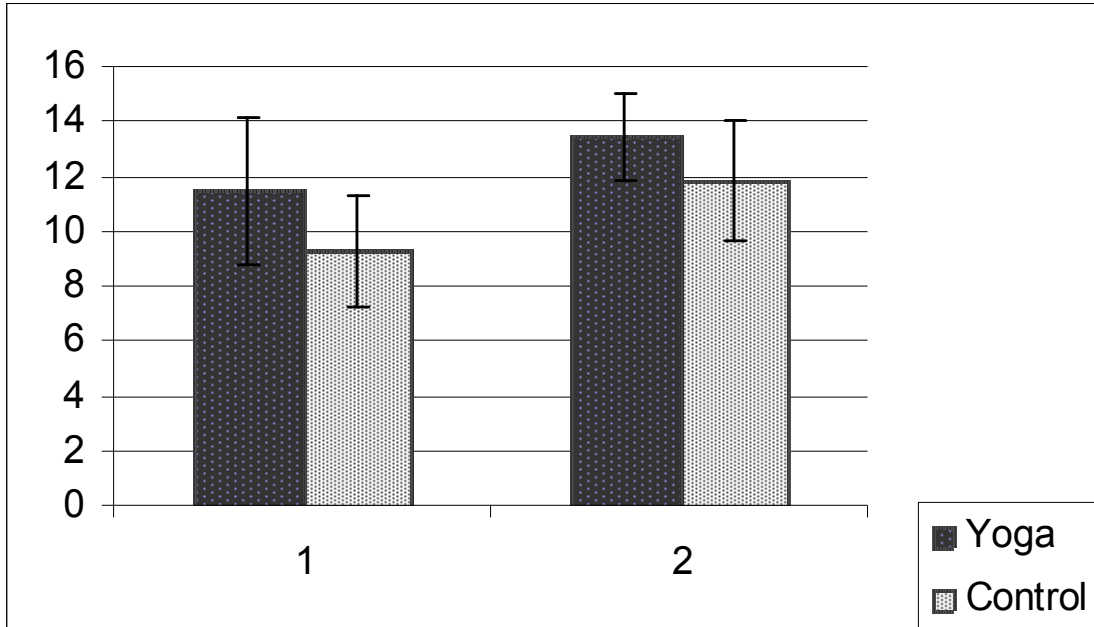
PGIMS-VIII (Verbal retention of dissimilar pairs) – Both groups showed significant increase ( $p < 0.001$  in yoga,  $p = 0.009$  in control group in Wilcoxon test). There was greater improvement ( $p < 0.001$ , Mann Whitney) in yoga group, the magnitude of change within group was more in the control (effect size 1.23) than the yoga group (effect size 0.90).

**TABLE-20: Results of Punit Govil Intelligence Memory Scale (PGIMS-VIII) showing the mean  $\pm$  SD in pre and post data of yoga and control group**

Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group $\wedge$ p	Effect size Pre-post	Y-C $\square$ p	Effect size Y-C	Normative data
<b>Yoga</b>	11.48 $\pm$ 2.67	13.46 $\pm$ 1.59	<0.001	0.90	<0.001	0.73	11 $\pm$ 3.59
<b>Control</b>	9.28 $\pm$ 2	11.85 $\pm$ 2.18	0.009	1.23			

\*  $p < 0.001$ , Pre v/s Post data of yoga and control group

**PGIMS - VIII**



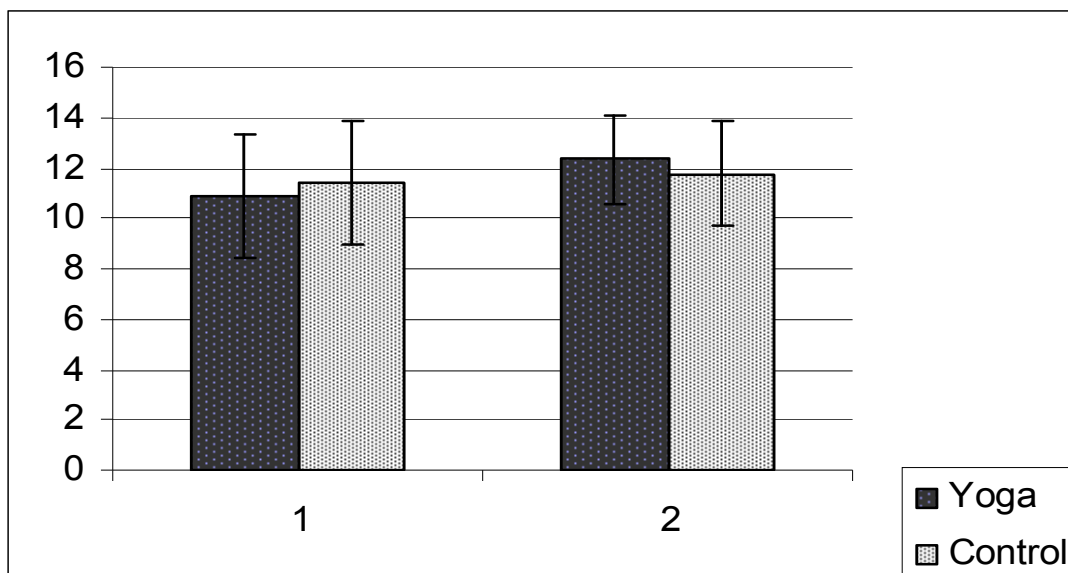
PGIMS-IX (Visual retention) – There was significant increase in yoga group ( $p < 0.001$ , Wilcoxon test) whereas no change in the control group ( $p = 0.39$ ). There was greater improvement ( $p = 0.01$ , Mann Whitney) in yoga (effect size 0.70) than the control group (effect size 0.14).

**TABLE-21: Results of Punit Govil Intelligence Memory Scale (PGIMS-IX) showing the mean  $\pm$  SD in pre and post data of yoga and control group**

Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group $\wedge$ p	Effect size Pre-post	Y-C $\square$ p	Effect size Y-C	Normative data
Yoga	10.85 $\pm$ 2.46	12.35 $\pm$ 1.76	<0.001	0.70	0.01	0.26	8.2 $\pm$ 3.28
Control	11.43 $\pm$ 2.46	11.76 $\pm$ 2.1	0.39	0.14			

\*  $p < 0.001$ , Pre v/s Post data of yoga and control group

**PGIMS - IX**



PGIMS-X (Recognition) – Both groups showed significant increase ( $p = 0.001$ , Wilcoxon tests) There was greater improvement ( $p = 0.001$ , Mann Whitney) in yoga (effect size 0.58) than the control group (effect size 0.28).

**TABLE-22: Results of Punit Govil Intelligence Memory Scale (PGIMS-X) showing the mean  $\pm$  SD in pre and post data of yoga and control group**

Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group $\wedge$ p	Effect size Pre-post	Y-C $\square$ p	Effect size Y-C	Normative data
<b>Yoga</b>	8.13 $\pm$ 2.37	9.37 $\pm$ 1.89	<0.001	0.58	0.001	0.37	8.36 $\pm$ 1.61
<b>Control</b>	7.57 $\pm$ 1.53	8.59 $\pm$ 1.4	<0.001	0.28			

\*  $p < 0.001$ , Pre v/s Post data of yoga and control group

**PGIMS - X**

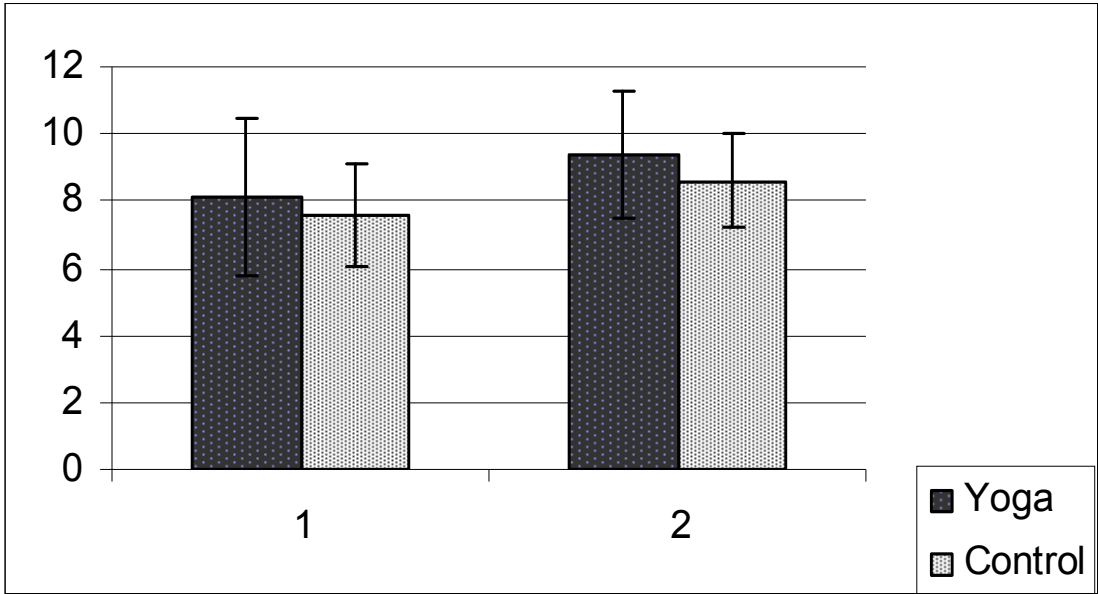


TABLE – 23

## Results of SLCT &amp; PGIMS

Variable	Groups	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	Within group $\wedge$ P	Effect size Pre-post	Between Y-C $\square$ p	Effect size Y-C	Normative data
SLCT	Y	27.43 $\pm$ 6.91	35.31 $\pm$ 6.72	< 0.001	1.16	< 0.001	0.8	30 $\pm$ 6
	C	26.48 $\pm$ 6.37	30.19 $\pm$ 6.63	< 0.001	0.6			
PGIMS I	Y	5.43 $\pm$ 0.66	5.87 $\pm$ 0.34	<0.001	0.84	<0.001	1.55	5.78 $\pm$ 0.52
	C	5.52 $\pm$ 0.67	5.17 $\pm$ 0.54	0.001	0.58			
PGIMS II	Y	4.94 $\pm$ 0.23	4.94 $\pm$ 0.23	0.83	0.00	0.080	0.01	4.91 $\pm$ 0.29
	C	5 $\pm$ 0.51	4.93 $\pm$ 1.15	0.439	0.08			
PGIMS III	Y	4.93 $\pm$ 1.15	6.52 $\pm$ 0.72	<0.001	1.66	<0.001	1.36	5.69 $\pm$ 2.64
	C	5.19 $\pm$ 0.93	5.33 $\pm$ 0.7	0.394	0.17			
PGIMS IV (i)	Y	5.39 $\pm$ 1.04	6.2 $\pm$ 1.14	<0.001	0.74	<0.001	0.94	**8.46 $\pm$ 1.91
	C	5.24 $\pm$ 1.11	4.83 $\pm$ 1.3	0.014	0.34			
PGIMS IV (ii)	Y	3.57 $\pm$ 1.09	4.19 $\pm$ 0.95	<0.001	0.61	<0.001	0.58	**8.46 $\pm$ 1.91
	C	4.17 $\pm$ 1.15	3.56 $\pm$ 0.74	0.001	0.63			
PGIMS V	Y	8.11 $\pm$ 0.88	9.33 $\pm$ 0.78	<0.001	1.47	<0.001	1.20	6.99 $\pm$ 1.53
	C	8.02 $\pm$ 0.9	8.17 $\pm$ 0.8	0.363	0.18			
PGIMS VI	Y	9.26 $\pm$ 1.51	11.13 $\pm$ 0.89	<0.001	1.51	<0.001	0.93	7.41 $\pm$ 1.98
	C	9.41 $\pm$ 1.5	9.98 $\pm$ 1.21	0.015	0.42			
PGIMS VII	Y	4.93 $\pm$ 0.26	4.98 $\pm$ 0.14	0.18	0.24	0.56	0.10	4.36 $\pm$ 0.78
	C	4.91 $\pm$ 0.29	4.96 $\pm$ 0.19	0.257	0.20			
PGIMS VIII	Y	11.48 $\pm$ 2.67	13.46 $\pm$ 1.59	<0.001	0.90	<0.001	0.73	11 $\pm$ 3.59
	C	9.28 $\pm$ 2	11.85 $\pm$ 2.18	0.009	1.23			
PGIMS IX	Y	10.85 $\pm$ 2.46	12.35 $\pm$ 1.76	<0.001	0.70	0.01	0.26	8.2 $\pm$ 3.28
	C	11.43 $\pm$ 2.46	11.76 $\pm$ 2.1	0.39	0.14			
PGIMS X	Y	8.13 $\pm$ 2.37	9.37 $\pm$ 1.89	<0.001	0.58	0.001	0.37	8.36 $\pm$ 1.61
	C	7.57 $\pm$ 1.53	8.59 $\pm$ 1.4	<0.001	0.28			

Note: Y=Yoga group; C=Control group; Mean  $\pm$  standard deviation and P values are calculated for PGIMS (10 subtests) using  $\wedge$ Wilcoxon p value;  $\square$ Mann Whitney p value. Variables: PGMIS-I -Remote memory, PGIMS-II -Recent memory,

PGIMS-III -Mental balance, PGIMS-IV (i) -Attention & Concentration (i), PGIMS-IV (ii) -Attention & Concentration (ii), PGIMS-V -Delayed recall, PGIMS-VI -Immediate recall, PGIMS-VII -Verbal retention (i), PGIMS-VIII -Verbal retention (ii), PGIMS-IX -Visual retention, PGIMS-X -Recognition test. \*\* This score is given in the PGIMS manual combining both Attention & Concentration (i) and (ii).

Foot note: There was greater improvement in yoga than the control group in SLCT: Improvement in yoga is better than control group and in all subtests of memory except II and VII.

### **6.3 Psychological variables**

The baseline values were not significantly different between yoga and control groups ( $p > 0.01$ ) for all the variables including age, serum FSH, BMI, psychological, somatic, vasomotor, perceived stress and extroversion except neuroticism (higher scores in yoga group).

#### **Comparison of GCS, PSS & EPI with normative data**

The scores in this study for psychological ( $6.18 \pm 3.48$ ), somatic ( $6.16 \pm 4.25$ ) and vasomotor ( $4.41 \pm 1.79$ ) were much lower as compared to the Scottish women (N=50) with ( $12.33 \pm 6.15$ ), ( $3.45 \pm 2.44$ ) and ( $2.31 \pm 2.04$ ) for the three factors respectively (Greene, 2007). The score for PSS (Cohen et al, 1993) is higher in the present study group ( $17.52 \pm 6.38$ ) than the normative values ( $12.60 \pm 6.10$ ) for American house wives. The values for extroversion and neuroticism in our population were also observed to be much lower ( $10.77 \pm 3.40$  and  $10.51 \pm 4.59$  respectively) than the normal scores ( $26.08 \pm 8.55$ ,  $17.37 \pm 10.10$  respectively) in American women (Eysenck & Sybil, 1971).

#### **Greene climacteric scale (GCS) - Table 24**

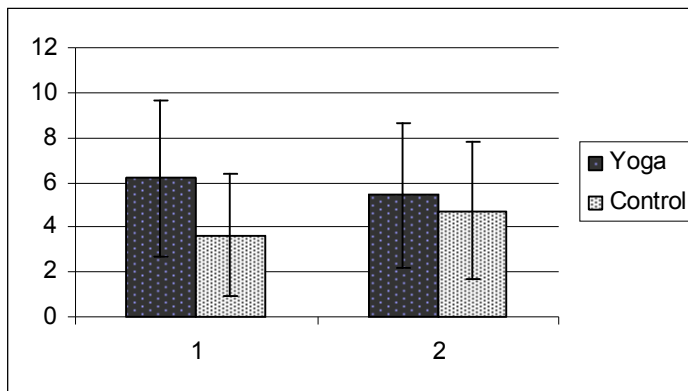
There was a significant difference ( $p < 0.05$ ) between groups in the vasomotor factor, a marginally significant difference ( $p = 0.06$ ) in psychological and no change in somatic component. Within group analysis showed significant improvement in all three factors in yoga group ( $p < 0.001$ ) and in only psychological factor ( $p < 0.05$ ) in control group. Effect sizes were higher in yoga group in all factors.

Factors	YOGA		CONTROL		Sig. †p		Effect size pre-post		Sig. ††p Y-C
	Mean ± SD pre	Mean ± SD post	Mean ± SD pre	Mean ± SD post	Y	C	Y	C	
<b>PSY</b>	6.18 ± 3.48	3.65 ± 2.76	5.42 ± 3.26	4.74 ± 3.04	<0.001	0.01	0.83	0.26	0.06
<b>SOM</b>	3.45 ± 2.44	2.16 ± 1.74	3.01 ± 1.90	2.16 ± 2.04	<0.001	0.22	0.74	0.19	0.19
<b>VAS</b>	2.31 ± 2.04	1.47 ± 1.30	2.16 ± 1.50	1.95 ± 1.30	<0.001	0.24	0.66	0.18	0.03

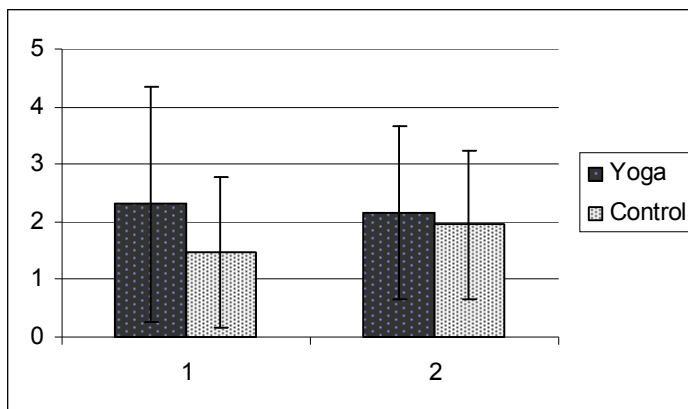
**TABLE – 24 Greene Climacteric Scale (GCS) results**

Note: PSY-Psychological, SOM-Somatic, VAS-Vasomotor symptoms; Y-Yoga group, C-Control group; Mean, SD, †p-Wilcoxon test, ††p-Mann Whitney test (only post results presented) calculated using SPSS version 10.0.

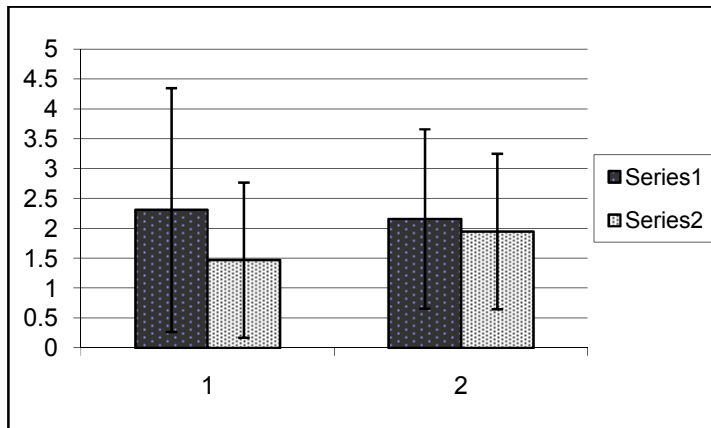
**GCS - PSY**



**GCS-SOM**



## GCS-VAS



### 6.3.1 Perceived stress scale (Table -25)

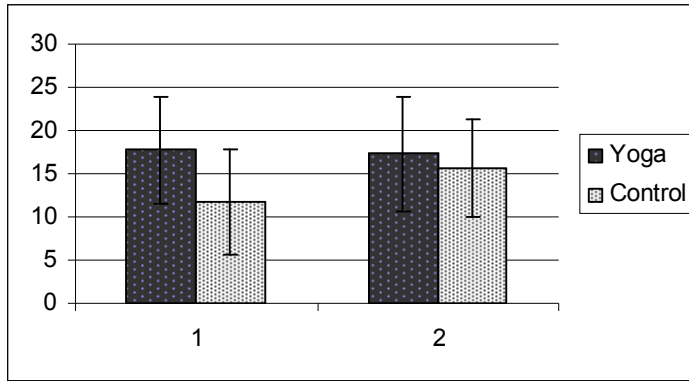
There was significantly greater degree of reduction in yoga group compared to controls (between group analysis) in PSS scores ( $p < 0.001$ ). The magnitude of stress reduction was more in yoga (effect size 1.10) than the control group (effect size 0.27).

**TABLE - 25 Perceived Stress Scale (PSS) results**

Groups	Mean $\pm$ SD Pre	Mean $\pm$ SD Post	Sig. †p	Effect size Pre-Post	Sig. ††p	Effect size Y – C
<b>Y</b>	17.74 $\pm$ 6.15	11.74 $\pm$ 6.15	< 0.001	1.10	< 0.001	0.66
<b>C</b>	17.3 $\pm$ 6.61	15.63 $\pm$ 5.61	0.003	0.27		

Note: Y–Yoga, C–Control; †p–Paired samples ‘t’ test, ††p–Independent samples ‘t’ test.

## PSS:



### 6.3.2 Eysenck's Personality Inventory (Table – 26)

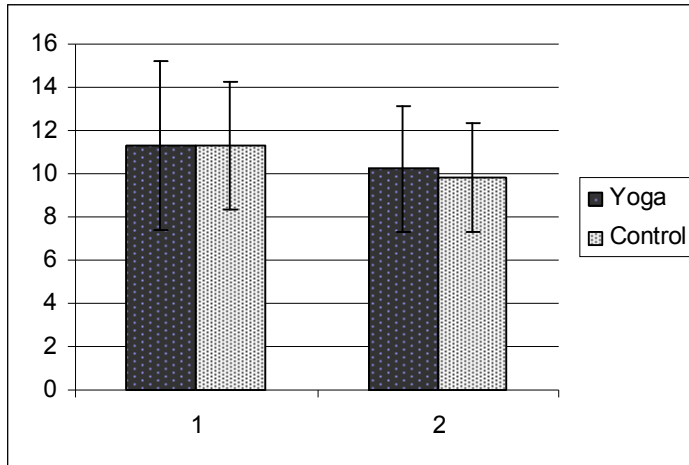
There was a greater magnitude of change in neuroticism in yoga group (effect size 0.43) than the controls (effect size 0.21) with significant differences between groups ( $p < 0.05$ ). Within group analysis showed highly significant decrease ( $p < 0.001$ ) within yoga group and no change in control group. There was no significant change in extroversion in both groups.

**TABLE – 26 Eysenck's Personality Inventory (EPI) results**

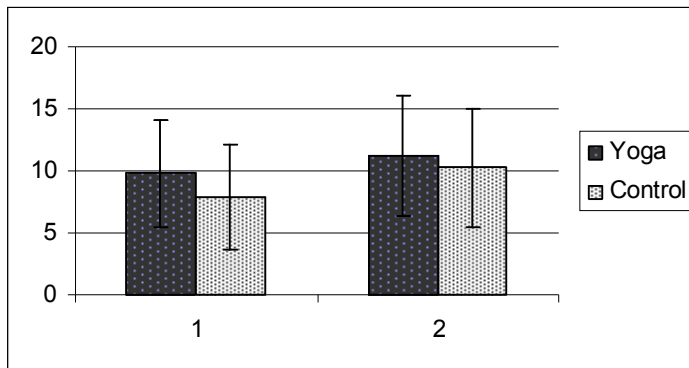
Variables	Mean $\pm$ SD Pre	Mean $\pm$ SD Post	Sig. †p	Effect size Pre-Post	Sig. ††p	Effect size Y – C
<b>Extroversion</b>	11.30 $\pm$ 3.88	11.31 $\pm$ 2.94	0.965	0.00	0.006	0.54
<b>Yoga</b>						
<b>Control</b>	10.24 $\pm$ 2.92	9.83 $\pm$ 2.49	0.315	0.15		
<b>Neuroticism</b>	9.78 $\pm$ 4.36	7.91 $\pm$ 4.28	< 0.001	0.43	0.009	0.51
<b>Yoga</b>						
<b>Control</b>	11.24 $\pm$ 4.82	10.24 $\pm$ 4.83	0.085	0.21		

Note: Y – Yoga, C – Control; †p - Paired samples 't' test, ††p - Independent samples 't' test.

### EPI-Extroversion



**EPI- Neuroticism**



Correlations among FSH, Age, GCS factors, EPI and PSS - Table 27

There was a positive correlation between FSH and age; and a negative correlation between FSH and extroversion of EPI; psychological symptoms of GCS were positively correlated with PSS and neuroticism of EPI; somatic symptoms of GCS positively correlated with PSS scores, neuroticism, FSH and age; vasomotor symptoms significantly correlated to PSS scores and neuroticism.

**TABLE 27** **Correlation matrix**

Variables	PSYCH	SOM	VAS	PSS	EXT	NEU	FSH	Age
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<b>PSYCH</b>	**1.00	**0.56	**0.40	**0.56	n.s	**0.61	n.s	n.s
<b>SOM</b>		**1.00	**0.44	**0.41	n.s	**0.43	n.s	*0.21
<b>VAS</b>			**1.00	*0.27	n.s	**0.44	*0.25	**0.34
<b>PSS</b>				**1.00	n.s	**0.48	*0.18	n.s
<b>EXT</b>					**1.00	n.s	- 0.22	n.s
<b>NEU</b>						**1.00	*0.20	n.s
<b>FSH</b>							**1.00	*0.19
<b>Age</b>								**1.00

Note: PSYCH-Psychological, SOM-Somatic, VAS-Vasomotor symptoms, PSS-Perceived Stress Scale, EXT-Extroversion, NEU-Neuroticism, FSH-Follicle stimulating hormone. \*p<0.05, \*\*p<0.001. ns – not significant correlation.

## 7. Discussion

Complimentary and alternative therapies have become the preferred treatment modality by women with promising results after hormone replacement was shown to be harmful for treatment of perimenopausal symptoms. The tradition of yoga appears to have a systematic conceptual basis and suitable techniques to handle the psychological and somatic symptoms of climacteric.

### STUDY – 1 Cohort design

#### Menopause Rating Scale

The website ([www.menopause-rating-scale.info](http://www.menopause-rating-scale.info)) devoted to the MRS has a compendium of results of the MRS studies done so far. Table 28 (adapted from this website) shows the factor loadings obtained from six previous studies and the last column of that table shows that factor loadings that this study has obtained.

**Table 6. Factor loadings from various studies**

Symptoms	Germany 1996 (479)			All countries 2002 (10297)			Europe 2002 (4791)			N America (USA) (1500)			Latin America 2002 (3006)			Indonesia (1000)			India 2007 (518)		
	P	S	U	P	S	U	P	S	U	P	S	U	P	S	U	P	S	U	P	U	S
Flushes(1)	0.8			0.7			0.7			0.7			0.5			0.9			0.8		
Heart(2)	0.7			0.8			0.7			0.7			0.9			0.6			0.7		
Sleep(3)	0.6			0.5			0.6			0.7			0.5			0.5			0.4		
Depress(4)	0.8			0.8			0.8			0.8			0.8			0.8			0.7		
Irritability(5)	0.7			0.8			0.9			0.9			0.8			0.8			0.8		
Anxiety(6)	0.8			0.8			0.8			0.8			0.8			0.8			0.9		
Exhaust(7)	0.6			0.7			0.6			0.6			0.7			0.5			0.6		
Sexual(8)	0.7			0.7			0.7			0.8			0.6			0.8			0.6		
Bladder(9)	0.8			0.6			0.6			0.6			0.7			0.5			0.7		
Dryness(10)	0.8			0.8			0.8			0.8			0.8			0.9			0.8		
Joints(11)	0.5			0.5			0.6			0.5			0.4			0.5			0.6		

All items are seen to have the same factor loadings except that item 3 (sleep problems) has a lesser factor loading than the ones in the other six studies. This same item has also shifted from being part of the somatic group to the psychological group for our Indian population. We have also analyzed the data using a varimax rotation and found that the item on sleep problems loads equally on both the psychological and the somatic factor (with a loading of about 0.46, the rest of the structure remaining the same). Of course, it is the oblimin solution that represents the better solution since there is a significant correlation between the factors (Table 4).

The other point of interest is that the urogenital factor assumes slightly more importance than the somatic factor in our population. (Thus, in Table 6, in the last column the factors are in the order 'P', 'U', 'S', in contrast to the other columns.) It is interesting to compare the three sub-scale scores of our study with global data available at the website in reference 9. Table 7 shows this comparison. The last row contains the means of the scores on the three sub-scales for our data. The score on the psychological factor for Indians appear to be more than that for the other countries, particularly the European/American scores, even taking into account the fact that this

factor has one item more for Indians (item 3) than it does for the others. Also, the total score for Indians (10.34) is comparable to the scores of the Latin American population (10.4) rather than the Indonesian (7.2). The difference between the Indian and Indonesian scores is marked and studies on other Asian populations are clearly desirable.

**Table 7. Scores on the three subscales**

<b>Samples</b>	<b>Psychological</b>	<b>Somatic</b>	<b>Uro-genital</b>	<b>Total</b>
<b>Europe</b>	3.4	3.6	1.9	8.8
<b>USA</b>	3.4	3.8	2	9.1
<b>Lat-Amer.</b>	4.9	4.1	1.4	10.4
<b>Indonesia</b>	2.9	3.3	1	7.2
<b>Wt. mean</b>	3.81	3.75	1.67	9.18
<b>India</b>	<b>5.59</b>	<b>2.96</b>	<b>1.78</b>	<b>10.34</b>

The last row contains the means of the scores on the three sub-scales for our data. The row marked “Wt. mean” contains the mean of the first three rows weighted by the sample size (not displayed in this table). The score on the psychological factor for Indians appears to be more than that for the other countries, particularly the European/American scores, even taking into account the fact that this factor has one item more for Indians (item 3) than it does for the others.

### **Greene Climacteric Scale**

Till the formulation of Greene’s climacteric scale in 1998, there seemed to be no standard instrument to assess the climacteric in women. The purpose of this replicative study was to set up normative data in the context of the menopause for the Indian population (Table 4) using the GCS. We have shown that Greene’s original model of three distinct factors (psychological, somatic and vasomotor) constitute a

good representation of the factors associated with the climacteric in Indian women. These three factors were present in Indira's earlier study (Indira & Murthy, 1980), but were just three out of eight factors. After the incorporation of some changes in the original scale of Greene, there has been no replicative study which confirms the factor structure. Our study fills this gap.

For normative purposes, we have noted that the study on an Ecuadorian population (Sierra et al, 2005) using the GCS also showed means for the sub-scales that are almost the same as the ones we obtain (Table 5). It is interesting to note that the means on each of the sub-scales are much lower than the ones given by Greene (1976) (even after accounting for the fact that the items in that study were slightly different). Another study that used the GCS on a Dutch population (Barentsen, 2001) gives a total score on the GCS of  $15.78 \pm 9.09$  which is almost the same as the total scores for this study and the study on the Ecuadorian population.

The hypothesis that the psychological scale should have two distinct facets (anxiety and depression) is shown to hold only when varimax (orthogonal) rotation is used. The other difference we noted when varimax rotation is used is that item 18 ("Breathing difficulties") is part of the anxiety factor rather than the somatic factor. However, both analyses show that the last item on the scale ("Loss of interest in sex") is clearly associated with the vasomotor factor.

This study aimed to report the prevalence of symptoms in Indian perimenopausal women and to construct symptom groupings from reported symptoms as there is not much information available on the experience of menopausal symptoms and their groupings in Asian women. The findings of this factor analysis may be used as normative data for future studies.

## **STUDY – 2 (Randomised control study to evaluate the efficacy of IAYT in climacteric syndrome)**

Cognitive functions and vasomotor symptoms were assessed in this randomized control prospective two arm interventional study on 108 perimenopausal women (age 40-55 years). Mann Whitney test to compare the two groups showed that there was significantly better improvement in the yoga group as compared to the control group in vasomotor symptoms and attention task (Six-letter cancellation test - SLCT). In Punit Govil Intelligence Memory Scale (PGIMS), remote memory, mental balance, attention & concentration, delayed and immediate recall, verbal retention and recognition tests showed a significant difference whereas no change was observed in these tests in the control group after the 8 weeks of yoga practice.

### **Comparison with other studies**

The preferred option for CAM by women (Wijma et al, 1997) has triggered interest into research on these therapies. Of the four studies (two on CBT and two on relaxation response) only one was a well designed RCT on 33 women taking relaxation response training (RR group) compared to a reading group, demonstrated a significant reduction in hot flush intensity, tension-anxiety and depression in perimenopausal women after 10 weeks of intervention (Irvin et al, 1996). There are no studies on changes in cognitive functions with non pharmacological therapies. In comparison the present study on IAYT that combined both body and mind level practices of self management (life style change) has shown significant improvement in both frontal lobe and memory functions for the first time through a non-pharmacological intervention. Findings from controlled treatment trials on physiological doses of ERT in postmenopausal women with probable Alzheimer

disease failed to show amelioration of existing deficits in cognitive functioning and / or prevention of further deterioration in memory that inevitably occurs in these women over time (Sherwin, 2003). A study on the interaction of HRT and physical activity (PA) showed a beneficial relationship between PA and cognitive performance in postmenopausal women irrespective of HRT use (Etnier & Sibley, 2004). These studies tend to point out that the self corrective techniques that the person puts in by applying her mind, be it a physical activity or IAYT, influences the cognitive functions.

### **Mechanism**

SLCT measures the attention capacity, a frontal lobe function. A self control study on the effect of cyclic meditation (that has been incorporated in the IAYT for the experimental group in the present study), has shown significant increase in SLCT scores immediately after CM suggesting enhanced efficiency and shorter time in cortical neural processing (Sarang & Telles, 2007).

**Electrophysiological studies during cognitive functions of the brain have reported that P300, (a specific positive wave that occurs at the 300<sup>th</sup> millisecond in the tracing of evoked potential) is generated from hippocampus & other associated areas (Halgren et al, 1998). Estrogen receptors (ER) have been detected in the pyramidal cells nuclei of the ventral hippocampus and other specific brain areas that are involved in learning, memory and cognition. Cyclic changes in synaptic genesis and spine-density of the hippocampus have been shown to be induced by estrogen (Vaidya et al, 2004), which gets depleted in this age; hence**

memory functions may undergo a declining change. However, contrary to our expectation, ERT per se may not improve the cognitive functions (Etnier & Sibley, 2004). A study on the effect of cyclic meditation observed that there was reduction in the peak latencies of P300 after cyclic meditation compared to the pre values which suggest enhanced efficiency and shorter time in processing. Also, the P300 peak amplitudes after cyclic meditation (CM) were higher as compared to the pre values suggesting an increased in attentional resources (Sarang & Telles, 2006). Thus it may be hypothesized that the improvement in the cognitive functions observed in this study is due to the effect of yoga in bringing about better information processing in the subtle layers of the frontal lobe. This in turn could be due to the alertful rest that cyclic meditation may offer and may not be related to estrogen-mediated response. CM developed on a subtle principle suggested by a rarely used authentic scripture (*Mandukya karika*) that includes stimulation-relaxation combination for achieving deeper degree of rest. This principle is made practical by knitting yoga postures interspersed with periods of supine relaxation and has been shown to provide deeper degree of rest than simple supine rest or the commonly used meditative techniques (Telles et al, 1994).

### **Comparison of baseline with normative values of GCS, PSS, EPI, FSH and Age**

The baseline values in this study on all variables were lower than the normative values provided in the manual (Ritu et al, 2007; Cohen et al, 1993; Eysenck & Sybil, 1971) except PSS. The most prominent difference was in the psychological and somatic symptoms of GCS, and extroversion score of EPI (Greene, 2007; Eysenck & Sybil, 1971). The differences in the scores could be explained by socio-cultural differences between the two countries (USA and India). The evidence from different surveys till date indicates that cultural differences in vasomotor symptom perception and reporting reflect both the underlying biological differences and an important socio-cultural factor ‘the attitude towards menopause’ (Crawford, 2007).

### **Compare physical exercise with climacteric syndrome**

The control group in the present study who practiced physical exercises for 8 weeks showed benefits with reduced perception of stress and the psychological symptoms. Physical activities of different types have been found to be beneficial in climacteric women. 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 equally effective in enhancing positive affect and menopause-related QOL and reducing negative affect (Elavsky & McAuley, 2007). In another study of 50 pre and post menopausal samples, the results of a 12 week exercise program provided only partial support for the role of aerobic exercise in reducing stress responses (Blumenthal, 1991), although both groups achieved comparable improvements in aerobic fitness.

### **Comparison with other studies on yoga**

There are three published studies on yoga in perimenopausal symptoms. Of these two were pilot studies which showed the beneficial effect and the other was the three armed study which showed no significant difference between walking and yoga. The present study has clearly demonstrated through an RCT, the superiority of yoga over physical activity in managing all the three climacteric symptoms, PSS and neuroticism. The difference could be in the duration and frequency of administration and the type of the practices in different studies. This was also observed by Waelde et al who concluded that the duration and frequency of practice of yoga seems to be important since the average minutes of weekly yoga-meditation practice had positive association with improvements in depression in their study on a six-session yoga-meditation program designed to help caregivers of dementia patients cope with stress (Waelde et al, 2004). To date we have many studies that provide evidence for the role of yoga in reducing anxiety, and depression in normal adult and geriatric population too. In a wait list control design, Iyengar yoga practice showed significant decreases in self-reported symptoms of depression and trait anxiety in 28 young adults (Woolery et al, 2004). Another three armed study in which IAYT was introduced to 69 old age institutionalized subjects showed significant reduction in their scores for depression in the yoga group at both 3 and 6 months (Krishnamurthy & Telles, 2007).

### **Mechanism of action**

Sympathetic arousal resulting in increased catecholamines and cortisol levels mediated through the HPA axis has been recognized to be the mechanism of increased stress, anxiety and the vasomotor and perimenopausal syndrome. Hence the documented evidences of reduction in these neurohumours and electrophysiological changes of sympathetic arousal after yoga practices had been proposed as its mode of action (Lucero & McCloskey, 1997; Wijma et al, 1997).

### **Mechanism, Stress, yoga, biochemistry (cortisol and GABA)**

In a study that compared 20 stressed and 20 nonstressed non-smoking premenopausal women between 42-52 years, the stressed women had elevated evening salivary cortisol indicating sympathetic arousal (Powell et al, 2002).

There are randomized control studies that have shown significant reduction in stress levels after yoga in subjects with mild to moderate levels of stress (Smith et al, 2007) and also a trend for higher morning cortisol levels after the period of study of 1-hour Iyengar yoga classes each week for 5 consecutive weeks (Woolery et al, 2004). McComb in his study on resting levels of stress hormones, physical functioning and submaximal exercise responses in women with heart disease undergoing an 8-week mindfulness-based stress-reduction (MBSR) program brought out the fact that just weekly once program for stress reduction is quite ineffective and fails to bring out change in stress hormone levels (Robert et al, 2004). An interesting study by Streeter et al suggests that the practice of yoga may reduce the depressive symptoms of perimenopause through increasing gamma-aminobutyric (GABA) levels in the brain. This study examined the GABA levels by measuring 'GABA-to-creatine ratio' in brain through magnetic resonance spectroscopy in normal adult yoga and non-yoga practitioners and showed a 27% increase in GABA levels in the yoga group after a 60 minute yoga session with no change after a reading session in comparison to non yoga practitioner group (Streeter et al, 2007).

### **Yoga and electrophysiology for sympathetic tone**

Reduced sympathetic tone through yogic relaxation techniques has also been documented. In a control study on guided yogic relaxation, significant reduction in heart rate, skin conductance levels, finger Plethysmogram have been reported. Also the spectral analysis of heart rate variability showed reduction in low frequency

(sympathetic tone indicator) and increase in high frequency (parasympathetic tone indicator) bands indicating reduced physiological arousal (Vempati & Telles, 1999). Another study on seven experienced meditators studied in two types of sessions i.e. meditation (with a period of mental chanting of "OM") and control (with a period of non-targeted thinking), there was a significant reduction in heart rate and increase in the cutaneous peripheral vascular resistance during meditation which is a sign of increased mental alertness, even while being physiologically relaxed (Telles et al, 1995).

### **Cyclic meditation and Rest**

A specific type of meditation called '*avartan dhyanam*' (cyclic meditation-CM) was incorporated as the main practice in the present study based on our earlier studies wherein it is shown that CM brings about a deep state of physiological rest. Two days of stress reduction program using CM in 26 executives with occupational stress showed a significant decrease in the power of low frequency component of the heart rate variability spectrum and LF/HF ratio and breath rate (Vempati & Telles, 2000). The oxygen consumption is considered as a general index of the metabolic rate during physiological activities (Schmidt et al, 1996). Significantly greater resting metabolic rate (RMR) was found in a high-trait anxious group than in a low trait anxious group (Grinde, 2005) suggesting that a higher rate of oxygen consumption may be associated with higher anxiety (Telles et al, 2000). A reduction in oxygen consumption has been reported following meditation practices and relaxation response (Vempati & Telles, 1999). A rarely quoted traditional yoga scripture (*Mandukya karika*) point to an interesting intrinsic mental phenomenon that, in a meditative technique that involves a series of alternating activity (physical movements or mental chanting) and non activity (relaxation or stoppage of internal dialogue) with

awareness, the degree of rest that follows will be deeper than the physiological rest achieved during only restful meditation in one posture and hence can facilitate stress release at deeper levels. During CM, the extremely slow, conscious movements of the body provide a high sense of sensitivity to grasp the subtle changes happening inside the body, which may go unnoticed in a simple meditative state (Nagendra & Nagarathna, 2004). The practice of CM reduced the oxygen consumption to 32% compared to the preceding period, as well as compared to a reduction of 10.1% with a period of supine rest of equal duration (Telles et al, 2000).

Despite the emergence of a range of nonhormonal treatments for menopausal symptoms, a need still exists for safe and effective therapeutic options that directly target the underlying thermoregulatory mechanisms for women who want treatment but prefer to avoid hormone therapy or for whom hormone therapy is contraindicated (Rapkin, 2007). Thus this study has shown the efficacy of integrated yoga in helping the perimenopausal women improve their inner mastery that could lead to better coping capacities, gracefully accept the change in their reproductive health, overcome stressors of ageing, combat anxiety and depression, thereby improve their personality to enjoy the freedom from the cycles of monthly menstruation and divert the energies towards spiritual growth.

Since yoga is popular as a complimentary and alternative therapy with >15 million persons (more women) practicing yoga in USA (Saper et al, 2004) and awareness amongst general practitioners (Hall & Giles-Corti, 2000), this study can add scientific evidence for the gynecologists to recommend it to their clients instead of prescribing pharmacological measures. Yoga, which is a self corrective technique when popularized as a treatment modality, not only can prevent and treat the perimenopausal syndrome but also can help in preventing many of the stress related

problems of modern life style that these women are prone to, after menopause. The philosophy and the practices of yoga provide a good field of study for internal experimentation during the 'empty nest' post retirement phase of life of a woman and helps her to grow in her personality to lead a healthy and happy life.

## **8. SUMMARY AND CONCLUSIONS**

### **8.1 Summary**

### **8.2 Conclusions**

#### **8.1 SUMMARY**

There is a limited amount of information on the experience of menopausal symptoms and their groupings in Asian women, the objectives of factor analyzing Menopause Rating Scale and Greene Climacteric Scale for Indian population were to report the prevalence of symptoms in Indian perimenopausal women and to construct symptom groupings from reported symptoms. The findings of the factor analysis on each scale may be used as normative data for future studies.

**In the single blind prospective randomized two armed study on 108 perimenopausal women, cognitive functions like attention, concentration, mental balance, immediate and delayed recall, visual and verbal retention and recognition abilities, climacteric symptoms, perceived stress and personality were assessed before and after eight weeks of intervention.**

**The study has shown that the practice of integrated approach of yoga therapy (IAYT) for eight weeks improves the cognitive functions like attention, concentration, mental balance, verbal retention and recognition abilities in menopausal women as compared to physical exercises.**

In Greene climacteric scale (GCS), there was a significant difference between groups in the vasomotor factor, a marginally significant difference in psychological and no change in somatic component. There was significantly greater degree of reduction in stress levels in yoga group compared to controls in Perceived Stress Scale (PSS). In Eysenck's personality inventory (EPI), there was a greater magnitude of change in neuroticism in yoga group than the controls. There were positive correlations between age and follicle stimulating hormone (FSH); and also between GCS, PSS and neuroticism scores.

The control group practices comprised of physical exercises also showed improvement in many of the memory functions similar to earlier studies on the efficacy of physical activity in perimenopausal women (Etnier & Sibley, 2004). Thus

the present study shows the superiority of yoga over physical activity in improving the cognitive functions which could be attributed to emphasis on correctness in breathing, synchronizing breathing with body movements, relaxation and mindful rest.

## **8.2 CONCLUSION**

The results suggest that integrated approach of yoga therapy (IAYT) could be one of the preferred nonhormonal, life style modifying regimes in perimenopausal women. Yoga has been spreading world over with its practitioners mushrooming round the globe. It has made its entry in the internationally acclaimed books, medical articles, therapy oriented magazines. Complimentary and alternative therapies have become the preferred treatment modality by women with promising results after hormone replacement was shown to be harmful for treatment of perimenopausal symptoms. Yoga is being considered one of the most important complementary and alternative therapy which is cost effective, without any side effects (if carefully practiced) and offers much more than mere healing. The tradition of yoga has conceptual basis and suitable techniques to handle the psychological and somatic symptoms of climacteric.

## **9. APPRAISAL**

### **9.1 Implications and Strength of the studies**

### **9.2 Limitations of the study**

### **9.3 Suggestions for future**

### **9.1 Implications and Strength of the studies**

**STUDY – 1**

1. After the incorporation of some changes in the original scale of Greene, there has been no replicative study which confirms the factor structure. Our study fills this gap.
2. As there is still a limited amount of information on the experience of menopausal symptoms and their groupings in Asian women, the MRS and GCS results report the prevalence of symptoms in Indian perimenopausal women.
3. The factor analysis of MRS and GCS constructed symptom groupings from reported symptoms.
4. The findings of this factor analysis may be used as normative data for future studies.

#### **STUDY – 2**

1. This is the first RCT that has looked at cognitive and psychological functions after yoga practice in climacteric.
2. An objective measure, serum FSH level, was used as the inclusion criterion rather than only the subjective symptoms of menopausal rating scale.
3. The type of practices for the yoga and control interventions was matched and the practices were supervised by trained instructors for the entire period of the study.
4. Control group also had the supervised practices for the same duration as the experimental group.

#### **9.2 Limitations of the study**

1. With regard to external validity, since the tests were in English, the sample was restricted to women with knowledge of the English language. Thus our sample should be taken to be fairly representative of women in urban India.

2. The estradiol levels were not measured. Although we have used FSH levels as the only objective inclusion criterion (Phillips, 2004). It will be interesting to see the effect of long-term practice of IAYT on FSH and estradiol levels.
3. This RCT included a highly selective group of women excluding those with associated illnesses such as diabetes and hypertension etc which are common diseases of this age, because this would interfere with the uniformity of the intervention and the resultant conclusions. This may bring in the question of generalisability of the application of the conclusions of this study in practice. Although there are earlier independent studies that have shown the benefits of yoga in diabetes and hypertension (Bijlani et al, 2005), it will be interesting to design studies that would recruit perimenopausal women with these common problems in future studies.
4. Since the significant benefits found in control group in psychological factor of GCS and PSS would lead to bias towards the null hypothesis in concluding the effects of yoga, inclusion of a third group who do not do any practice, in the design of the study, would throw light on the true treatment effects.

### **9.3 Suggestions for future**

1. Functional studies to look at the changes in neuro- hormonal changes in the brain, autonomic functions during mental stress challenge before and after the integrated approach of yoga therapy (IAYT) in perimenopausal women would throw light on the mechanism.
2. Inclusion of vasomotor symptom diaries as another variable could provide more detailed information about the efficacy of the intervention.

3. This study has shown the benefits in Indian women. It will be useful to conduct similar studies in other races where yoga may not be available as a traditional practice in their culture.

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