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

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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
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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).

**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) 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 8th 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 ‘α’ 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:

\[ S_d = \sqrt{S_{a}^2 + S_{b}^2 - 2r_{ab} S_{a} S_{b}} \]

where \( r_{ab} \) = Correlation Coefficient between After and Before data.

\( S_d \) before = 1.74

\( S_d \) after = 1.11

\( r \) = not known, so assumed 0

\( S_d \) of the difference = 2.05

\[ d = \frac{X_{a} - X_{b}}{S_d} \]

where \( X_{a} \) : mean of after data

\( X_{b} \) : mean of before data

\[ d = \frac{2.33 - 1.25}{2.05} = \frac{1.08}{2.05} = 0.52 \]

X2.05
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 sample size:

\[ n = \frac{1}{\left( t_{\alpha/2, \nu} + t_{\beta(1-\alpha)} \right)^2} \frac{d^2}{\nu} \]

Where \( \nu \) 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 Electrochemiluminescence’s method in Anand Diagnostic laboratory, Bangalore) on the 6th 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 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 *Munḍākya 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 (*Ardhakaṭicakrāsana* for 1:30 minutes); a gap of 1:30 minutes in *tāḍāsana* with instructions about relaxation and awareness; bending to the left (*Ardhakaṭicakrāsana* 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 (*Usṭrasana* 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.

### 4.2.1.1 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 *Mundaka Upaniṣat Kārikā*:

लये सम्भोधयेत् चित्रं बिशिष्ठं शम्येत्, जुनः।

सक्षरायं कंठानीयान्त समप्रायं नो चालयेत्॥ ३.४४ ॥

*Laye sambodhayet cittaà vikñiptaà çamayet punaù,*

*Sakañāyam vijñānīyāt samaprāptaà 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’

(*Mundāka 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 (sādhanā) 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 (kauśala) 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 vijñāna, one should know; that mind to be Sakaśāyanya, 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 (*kaśāya*) 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 *Mūṇḍūka Upaniṣat Kārikā* that:

```
यद्य न लियते चित्तं न च विक्षिप्तते पुनः ||
अनिन्दनमानसं निजपति वशस्तरं \|\| ||
```

*Yadā na liyate cittaṁ na ca vikṣipyate punaḥ. *

*Añiṅganamanābhāsaṁ nispannaṁ 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 (*anābhāsaṁ*); then it gets absorbed and becomes pure expansive Councioueness (*nispannaṁ brahma*).’ (*Mūṇḍūka 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):

\[
\text{स्थिरसुखमासनम्} \quad \text{Sthirasukhamāsanam. (PYS: 2.46)}
\]

\[
\text{प्रयत्नसायथित्यान्तरप्रतिभ्याम्} \quad \text{Prayatnaśaithilyāntarapratibhyām. (PYS: 2.47)}
\]

\[
\text{ततो द्वन्द्वनिभिष्टः} \quad \text{Tato dvandvānabhiṣṭaḥ. (PYS: 2.48)}
\]

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 (\( prayatnaśaithilya \)) (iii) mindfulness (\( sākṣi bhāva \)) (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 *Muṇḍūka 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 (*tāḍāsana, ardhakaṭicaṇkrāsana, pāḍahastāsana and ardhacakraśana*) 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 (*śaṣāṅkāsana and uṣṭrāsana*) are
interspersed with IRT (instant or isometric relaxation technique), QRT (quick relaxation technique) and DRT (deep relaxation technique).

Figure 4.2.1.1b: Postures in cyclic meditation.

Tāḍāsana  Aardhakaṭīcakrāsana  Aardhakaṭīcakrāsana
(Right side)  (Left side)
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 6th 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
Factor 3 (Urogenital) Items 9 – 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).

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 ± 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
rewarded 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