## CHAPTER – 5.0

### METHODS

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5.0 METHODS

5.1 NORMATIVE STUDY PROTOCOL

SUBJECTS

Sample size calculation, $\alpha = 0.05$, Confidence level = 99%, Population Size = 20000, and response distribution = 50%. Estimated sample size was = 643.

(http://www.raosoft.com/samplesize.html)

A total of 1297 volunteers were measured from December 2013 to December 2014, from different parts of India. Among them, 880 volunteers were reported to be healthy, (age M±SD, 33.55±10.92), with 584 males, (age M±SD, 33.54±10.86) and 296 females (age M±SD, 33.56±11.00). As the focus was to develop norms for healthy people, we did not include data of those with any self-reported ailments.

INCLUSION CRITERIA

The present study included only healthy Indian subjects of both genders, age range 18 to 60 years, and those who were willing to take part in the study.

EXCLUSION CRITERIA

The exclusion criteria were: any cut in fingers and/or absent fingers; subjects who had any self-reported health issues and if they had smoked or taken alcohol on the day of measurement.

5.2 CYCLIC MEDITATION VS SUPINE REST STUDY PROTOCOL

SUBJECTS

Sample size calculation:
Pilot study on \( n=20 \), \( \alpha = 0.05 \), \( \beta = 0.95 \), \( d = 1.04 \), estimated sample size \( n=42 \). (G*Power 3.0.10).

One hundred and fourteen managers participated in the study from a series of programs called self-management of excessive tension (SMET), which is conducted periodically at S-VYASA University, Bengaluru, India. All the subjects participating in the study were from 2 days of SMET program conducted for three companies in India viz., Hindustan Aeronautics Limited, Oil and Natural Gas Corporation Limited and Canara Bank.

**INCLUSION**

Age ranges 30–60 years, managers (having lifestyle related health issues), only male gender and willing to participate in the study and have no prior experience of yoga and meditation were included.

**EXCLUSION**

People with cut in fingers and absent fingers, undergoing any other wellness strategy and those who have smoked or taken alcohol or drugs on the day before the measurement were excluded.

### 5.3 INTEGRATED YOGA MODULE STUDY PROTOCOL

**SUBJECTS**

Pilot study on \( n=10 \), \( \alpha = 0.05 \), \( \beta = 0.80 \), \( d = 0.34 \), estimated sample size \( n=54 \). (G*Power 3.0.10).

Total of 152 volunteers attending one month of Yoga Instructor Course (YIC) were assessed before and after four weeks of their program. Participants from four different
batches of the YIC (May-2014, n=43, June-2014, n=52, July-2014, n=38 and August-2014, n=19) at Swami Vivekananda Yoga Anusamdhana Samsthan (S-VYASA, Yoga University), Bangalore, Karnataka, India, were considered for the study.

**INCLUSION CRITERIA**

Healthy volunteers, age ranging from 18 to 60 years, both male and female, willing to participate in the study and having post hoc Integral Area value between -0.6 to +1 (range of normal health index in EPI system for the EU population) were included within the study.

**EXCLUSION CRITERIA**

Volunteers who had cut in fingers, absent fingers, having any health-related issues, substance abuse were excluded from the study.

**5.4 ETHICAL CONSIDERATION**

The protocol was approved by the Institutional Ethics Committee (Appendix-6). All the participants were informed about the study and the assessments before conducting the study and the signed informed consents were obtained from all the subjects. They were thus conversant with the aims and objectives of the study as well as the intervention modules and their confidentiality was maintained.
5.5 DESIGN

1. Normative study

It is a normative study following a survey design in which data collection was done only once from all participants.

2. Cyclic Meditation VS Supine Rest

This is a two-group comparative design, in which all the subjects were randomised into two groups, CM and SR, using GraphPad software, an online program. EPI readings were carried out before and after 35 min of interventions, within 10 min for pre-assessment and 5 min for post-assessment.

3. Integrated Yoga Module

It is a single arm prospective study, in which four experiments were carried out on four different YIC programs. All subjects were assessed before and after four weeks of their YIC course.

5.6 INTERVENTIONS

CYCLIC MEDITATION VS SUPINE REST

Self-management of excessive tension program includes theory lectures on the concept of stress and its management and followed by practical sessions of CM. Apart from this, all the subjects also attend Morning Prayer and evening devotional session (Bhajan) as a part of daily activity in the residential setup.

CYCLIC MEDITATION
The basis of this CM is stimulation followed by relaxation, which gives profound rest in periodic cycles. CM is a module in which asana is an inherent component. This module CM has been tested in earlier studies investigated various physiological, neurophysiological and psychophysiological variables in comparison to SR (yogic method of relaxation). Previous studies have used the CM practice that lasts for 22 min and 30 s (Subramanya & Telles, 2009b). Present study involves 35 min of CM practice, divided into eight steps.

Step-1: Opening prayer (1 min), the practice began with lead and follow of verse from a yoga text, the *Mandukya Upanishad* (Lokeswarananda, 2005). Step-2: Instant relaxation technique (1 min), it is done by isometric contraction of the muscles of the body and ends with SR. Step-3: Centering (4 min); coming to standing position namely, *Tadasana* with both feet planted firmly on the ground followed by *Brahmari* chanting. Step-4: Standing posture called *Ardhakatichakrasana* (6 min) from *Tadasana* bending toward the right (1 min and 30 s); a pause of 1 min and 30 s in *Tadasana*, then bending toward the left (1 min and 30 s); a pause of 1 min and 30 s in *Tadasana* again. Step-5: Quick relaxation technique (5 min), in the SR with guided instructions and ends with the chanting of AAA (*A-Kara*) with an open mouth. Step-6: Sitting postures, *Vajrasana*, *Shashankasana* and *Ushtrasana* (6 min), coming to *Vajrasana* (1 min), bending forward (*Shashankasana*, 1 min and 30 s, followed by *M-Kara* chanting) a pause of 1 min and 30 s in *Vajrasana*, bending backward (*Ushtrasana*, 1 min and 30 s, followed by *A-Kara* chanting); a pause of 1 min and 30 s. Step-7: Deep relaxation technique (10 min) slowly coming to the supine position for further relaxation of
different parts of the body in a sequence as per instructions. Step-8: Closing prayer (2 min), the practice session is concluded with a prayer for the welfare of all.

SUPINE REST

The second group was given an equal duration of 35 min of SR in which subjects were lying down on a mat in the corpse posture (Shavasana). This is done with eyes closed, hands half feet away from the body, palms facing upward, legs apart at one and half feet distance and adopting a comfortable posture for 35 min.

INTEGRATED YOGA MODULE

Integrated Yoga Module for four weeks comprises of Kriyas (cleansing techniques), Asanas (Physical postures), Pranayama (Breathing practices), Dhyana (meditation), Bhajan (devotional songs), Krida Yoga (Yoga games), spiritual discourses and lectures on yoga and philosophy. The program starts daily at 4.30 am till 10.00 pm and the diet is vegetarian (yogic food).

5.7 ASSESSMENT TOOL

The EPI Camera Pro and compact instrument made by Kirlionics Technologies International, Saint-Petersburg, Russia were used for assessment.
Assessment through EPI is carried out in two ways: (a) With filter (known as physiological level of evaluation) and, (b) without filter (known as psychophysiological level of evaluation) (Korotkov et al., 2012). Filter is a specially designed thin plastic film. During the measurement process, a filter is placed between the fingertip and the dielectric glass plate which helps to eliminate sweat effects due to sympathetic responses and provides information which is of physiological only (Korotkov et al., 2012). Comparison of these images acquired in two different ways forms a parameter called activation coefficient. This parameter has proved very stable and accurate with EPI/GDV studies in the last 15 years (Korotkov et al., 2012). Activation Coefficient (AC) is an absolute magnitude of differences of coefficients of diagrams created using EPI-images captured with and without filter taking corresponding dispersions (Korotkov, 2002b), which is a quantitative assessment of stress level in a person, based on evaluation of autonomic balance (Korotkov, 2002a). This AC (EU population based) is scaled from 0 to 10 where 0–2 is a value for calm
and relaxed people. However, this range 0–2 may be due to two possible conditions: either the person is in very deep meditation or chronic depression. Values 2–4 are indicative of normal state; 4–6 is seen in an excited state, hence is indicative of more stressful conditions; 6–8 represents higher levels of stress; and finally, 8–10 is a condition of high level of stress (Korotkov et al., 2012). Further, the experimental data correlating the findings of EPI measures with heart rate variability (HRV) (Cioca, Giacomoni, & Rein, 2004), systolic and diastolic pressures (Aleksandrova et al., 2011), and the stress level (Korotkov, 2011a) suggest that EPI measures activity of autonomic responses.

Two more important component of Electro photonic imaging that are driven using various mathematical algorithm in EPI system are Integral Area and Integral Entropy. Integral Area (IA) is a measure of general health index of the person being investigated (Korotkov, 2002b). The normal range for IA (EU population based) is (−0.6 to + 1), corresponds to a good health state. The second constituent Integral Entropy (IE) is a measure of chaos/disorder in the energy pattern of human energy systems (Kostyuk et al., 2011). Entropy in the EPI system ranges (1 to 2) is considered normal as per the European norms.

5.8 DATA TAKING PROCEDURE

To obtain reliable and reproducible data, we followed an established guideline (Alexandrova et al., 2002). It is recommended to collect data after 3 hours of food intake and after 5 hours of any prescribed medications. No other diagnostic procedure was to be held at the same time. They were assessed before and after the respective
interventions, and the EPI readings were taken by the same expert, at the same place. There were identical conditions of psychological and physical comfort for all Subjects in a quiet and calm environment. Calibration of EPI device was performed routinely as per the guidelines. Subjects were instructed about finger placement on the glass at 45° angles with a gentle but firm touch. They were asked to remove all metallic ornaments that they do not wear for the entire 24 hours a day. Further, a few more things were followed for acquiring consistent readings: (1) The subjects stand on an electrically isolated surface while making a measurement; (2) the measurements were taken first with the filter, then without filter; (3) an alcoholic solution was used to clean the glass plate after every subject; and (4) a distance of three feet was maintained between EPI and a dedicated laptop computer while collecting data (Yakovleva & Korotkov, 2015b).

(The next chapter deals with data collection, extraction and analysis)