

CHAPTER 5

METHODS

5.0 METHODS

The previous chapter dealt with aim, objectives, hypothesis and null hypothesis, and how the study would benefit the caregivers (CGs) of children with neurodevelopment disorders (NDDs). This chapter will discuss the method and methodology adopted to carry on the intervention of canons of expression (CE) in Indian Aesthetic Dance (IAD) and yoga on CGs of children with NDDs.

5.1 PARTICIPANTS

5.1.1 Sample size: The sample size was calculated using G-Power software by fixing the alpha at 0.05 powered at 0.8 and an effect size of 0.21 based on the mean and standard deviation of the previous study (Vetter et al., 2011).

5.1.2 Selection and source of participants: Participants included caregivers from three different special schools, namely Nachiketa Manovikasa Kendra, Vijaya Nagara, Dharithree Trust, Peenya, and Aruna Chetana, Malleshwaram Bengaluru, India recruited between August 2018 to November 2018 to participate in 8-weeks canons of expression and yoga interventions.

5.1.2.a] Recruitment procedure of samples: Figure 5 shows the profile of the trial of samples on the CONSORT flow diagram. Caregivers were called by the school authorities who arranged a meeting. They were addressed about the purpose of the study in brief. 150 participants were assessed. Qualified participants were asked to consult physicians and psychologists to make sure that they are not diagnosed with severe neurologic and psychiatric disorders and not under any medication for chronic diseases. A total 101 participants were qualified and randomized into three groups. During the intervention, some participants dropped out, and data of the remaining 96 participants were analyzed at pre (baseline), mid (end of week 4), and post-intervention (end of week 8) with psychological questionnaires. The baseline

demographic characteristics of 96 caregivers who completed data collection are given in Table 12. Caregivers had the children belonging to following categories: Ten children belonged to Autistic spectrum disorder, seventy were affected with mental retardation with moderate and severe degrees, and other twenty-one had multiple problems such as down's syndrome, hyperactivity, hearing and speech problems, cerebral palsy, ADHD, borderline disorder, temper tantrum, William's syndrome, and behavioral disorder.

Parameters of Electro Photonic Images [EPI] were taken on the first day-pre (prior to intervention) and post (immediately after intervention). Among 96 subjects, only 91 were available for data collection of EPI parameters.

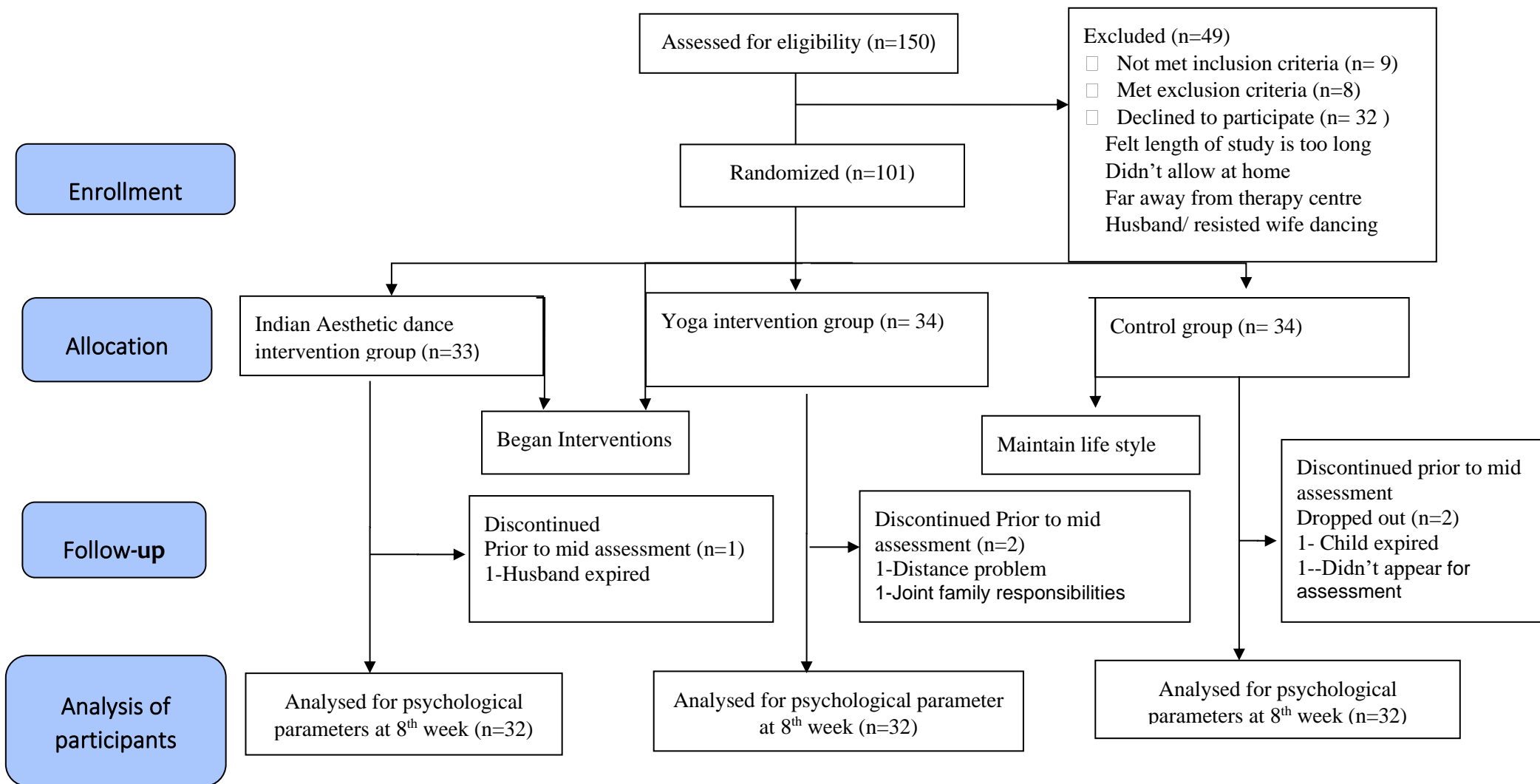
5.1.3 Inclusion criteria: participants were included in the study if they were:

- Of both genders, aged 21-65.
- Primary caregivers of children with behavioral and developmental disorders.
- Understand Kannada, English, or Hindi.
- Willing to participate in the decided number of classes.

5.1.4 Exclusion criteria: Participants were excluded under the following conditions.

- Caregivers diagnosed with severe neurologic and psychiatric disorders.
- Caregivers, having another relative with neurologic and psychiatric illness.
- Caregivers, under medication for chronic diseases.
- Caregivers, having formal yoga training from a recognized institute and practicing yoga regularly for the past 1 month.

Figure 5: Trial profile of participants' recruitment (n=96) for psychological tools



5.1.5 Ethical consideration

The study was approved by the Institutional Ethics Committee of University (RES/IEC-SVYASA/127/2018), and the research protocol was registered in the Clinical Trial Registry of India (CTRI/2018/08/015256). Signed informed consent was obtained from the head of the institution, and from each participant, upon explaining the study details.

5.1.6 Screening tool

Zarit burden interview was used to assess the level of stress in caregivers. This inventory has a series of 22 questions about the impact of the disability of their dependents on their own life. The questions focus on areas of CGs' health, psychosocial well-being, finances, social life, and the relationship between the caregiver and caretaker. This tool uses the subscale on 4 aspects, such as personal strain, privacy conflict, guilt, and uncertain attitude. The ranges of answers to each question were "never, rarely, sometimes, quite frequently, or nearly always." The total score ranges from 0 to 88. The higher ZBI scores indicate, the greater the burden. There is no indication of burden at scores of less than 21, the mild burden at 21–40, the moderate burden at 41–60, and severe burden at 61–88 (Limpawattana et al., 2013).

5.2 DESIGN OF THE STUDY

It was a single-blind pre-mid-post randomized controlled trial where all participants were randomly divided into three groups: (i) canons (dance based on standard elements) of expression (ii) yoga, and (iii) control. Before randomization, each participant was assessed at the baseline.

5.2.1 Randomization

Based on the scores of the burden scale, total 101 participants (males= 2; and female= 99) were randomized into three groups using a computer-based random number generator. (www.randomizer.com). Totally, 101 envelopes were prepared, and each participant was asked

to pick an envelope. Depending on the number in the envelope, participants were considered either in canons (standard elements) of expression (n=33, mean age 41.71 ± 9.11 years), or yoga (n=34, mean age 41.03 ± 9.09 years), or control (n=34, mean age 41.56 ± 9.09 year) group {known as sequentially numbered opaque sealed envelopes (SNOSE) randomization technique}.

5.2.2 Blinding

The statistician (who did the randomization and analyzed the data) was blinded to the source of the data.

After randomization, all other psychological inventories were administered. For those not able to read, the educated staff of the institution helped in explaining and marking the questionnaires. Further, Electro photonic image (EPI) parameters were taken pre and post-intervention using the bio-well instrument, a novel method to assess energy level (Bundzen, p. 2002) to see the immediate effect of the intervention. The intervention sessions were given three times a week, alternately for two months.

5.3 VARIABLES STUDIED (Outcome measures)

The primary outcome measures of the study are given in the following order: (i) Zarit Burden Inventory (ZBI), (ii) Depression Anxiety Stress Scale (DASS-21), and Secondary outcome measure (i) Revised Caregivers Appraisal Scale (RCAS), (ii) World Health Organization's Quality of Life (BREF) (WHOQOOL-BREF-26) scale and (iii) Bio-Energy components through Electro photonic image (EPI) technique.

5.3.1 Primary Outcome Measures

5.3.1.a Socio-Demographic Questionnaire

A socio-demographic profile was used to record the details of the participants such as age, gender, education, marital status, family income, the illness they have, detail about their

children such as their age, disorders, duration of their illness, diagnosis carried out, improvement thereafter, etc.

i) Zarit Burden Inventory (ZBI):

English version of ZBS containing 22 items with a 5-point scale was used in this study. This tool uses the subscale on 4 aspects, such as personal strain, privacy conflict, guilt, and uncertain attitude. The ranges of answers to each question were “never, rarely, sometimes, quite frequently, or nearly always.” The total score ranges from 0 to 88. The higher the ZBI ratings indicate, the greater the burden. (Hashimoto et al., 2017).

ii) Depression Anxiety Stress Scale (DASS-21)

It is a screening tool for identifying, differentiating and assessing Depression, Anxiety, and Stress initially used for patients with spinal cord injury (SCI). The subscales are three negative emotional states, namely, depression, anxiety, and stress. It is in a self-report format consisting of statements referring to the past week, and administering time should be less than 10 minutes. It is a 4-point scale (0-did not apply to me at all to 3-applied to me very much or most of the time). A high score indicated a greater level of distress. Correlation of Anxiety subscale is $r=0.61$; Depression subscale $r=0.70$ (Cox et al., 2005).

5.3.2 Secondary Outcome Measures

i) Revised Caregivers Appraisal Scale (RCAS)

Caregiving appraisal was assessed using 24 items CAS developed by Lawton and his colleagues (2000) for caregivers of disabled children. It measures the following dimensions: (1) Subjective caregiving Burden (9 items), (2) Perceived Environmental Impact (3 items), (3) Caregiving Mastery (6 items), and (4) Caregiving Satisfaction (6 items). The caregiver was asked to specify the amount of agreement with the statement of each item with a 5-point Likert rate (1=not at all, 5=a great deal). Higher scores on these scales indicated more burden, negative

impact, satisfaction, or mastery, respectively. Caregivers' burden $\alpha = 0.89$, perceived environmental effect $\alpha = 0.79$, Caregiving mastery $\alpha = 0.73$, Caregiving Satisfaction $\alpha = 0.87$. Test-retest reliabilities range from .75 to .78 (X. Wang, 2013).

ii) World Health Organization Quality of Life Scale-BREF (WHOQOL-BREF)

It is a 26 items integrated instrument addressing 4 domains: Physical health (7-items), Psychological health (6-items), Social relationship (3-items), and environment (8-items). Items are rated on a 5-point Likert scale (low score of 1 to high score of 5). Subsequently mean score of each item is calculated, resulting in a mean score per domain between 4 and 20. A higher score indicating higher QOL. Cronbach's α is physical health 0.82, psychological 0.81, social relationships 0.68 and environment 0.80 (Skevington et al., 2004).

iii) Electro Photonic Image (EPI):

The EPI technique is a scientific method based on the Kirlian effect (K. Kushwah et al., 2016) on coronal electrical discharge surrounding an object when exposed to a high electrical field (Hwa Chiang Lee et al., 2005). The EPI facilitates the assessment by placing the fingertips on a dielectric glass plate of the instrument and stimulation of electrons at the fingertips. It happens by applying a short electric pulse of a high voltage (10 kV) at high frequency (1024 Hz) but the low current that is in micro Amperes (Wróbel et al., 2010). The electrons drawn out in this way induce ionization of the air molecules and produce a glow around the finger. This glow, captured by a CCD-camera placed underneath the glass plate, is known as the electro-photonic image (Konstantin Korotkov et al., 2004). Further, these EPI images are collected from all 10 fingers of both the hands in two methods, i.e., with filter and without a filter. A filter is a specially designed thin plastic film placed between the finger and the dielectric plate during

the assessment that eliminates sweat effects due to sympathetic (psychosomatic) responses and procures only the physiological functional state of the person (Konstantin Korotkov et al., 2012). Further, these acquired images with and without a filter will be compared, which forms a parameter called Activation Coefficient, and based on the evaluation of autonomic balance, it forms a quantitative assessment of the stress level of a person (K. Korotkov, 2002).

5.4 INTERVENTIONS

Participants in canons of expression and yoga received 75 minutes (3 days /week) of integrated dance and yoga intervention for two months. A total of 24 sessions were scheduled across two months. All practices included in both the intervention group were safe, feasible. Scholars accepted the module of canons of expression, and the yoga module was authenticated by the previous study (Jagannathan et al., 2012). An attendance register was maintained to monitor the attendance of the participants. A cut-off of 70% attendance was kept to consider for analysis of participants.

Intervention on canons of expression was given by an experienced trainer having more than 20 years of experience. Similarly, yoga intervention was administered by a qualified instructor having more than 15 years of experience. The control group was engaged in their regular activities. The study was conducted in three different locations, one after the other, to provide the same module of dance and yoga intervention with similar quality. The control group was offered the same dance and yoga intervention after eight weeks of waiting.

(i) Intervention of canons of expression in Indian Aesthetic Dance

Indian aesthetic dance is a holistic approach with a bundle of innumerable classical movements, dialogue delivery, and facial expression of feelings intensified through lyrics (Ghosh, 2012), and it is not feasible to expect that a single element can yield desired result (Hiriyanna M.,

2000). The dance group began with warm-up exercises to help the untrained physical constitution of the participants (Kattenstroth et al., 2013) to facilitate flexibility of joints, reduce lethargy (C. D. Lima et al., 2016). It is followed by miming their negative incidents by participants in connection with their disabled children or family member for which disabled children being the reason, which pushed them into emotional dysregulation / psychological burden or increased stress, anxiety, or depression. The purpose was to help them express frozen anger, disgust, grief, and other negative emotions, which made them, neglect or dislike their children or family members. In the next step, varieties in hand gestures and movements of various parts of the body movements, i.e., hand, neck, head, eyebrows, eyes, shoulder, chest, waist, thighs, shanks, feet were taught as per *Nāṭyaśāstra* magnum opus, dating back to 1500 B.C (Subrahmanyam, 2003) to identify and enjoy aesthetic beauty in participant's limbs (Ghosh, 2012). Simple steps followed it in the coordination of all the parts of the body mentioned. Participants were trained for a dance without music until the steps of the dance were understood and comfortably performed. Then they were trained for step sequences with increased complexity (Kattenstroth et al., 2013) with slow and medium tempo music. The level of rhythm and tempo of the music allowed the participants to move their bodies at a required angle with consideration of safety.

A small piece of lyrics on positive emotions set to aesthetic tunes based on Indian music was taught along with facial expressions to lyrics to induce positive emotions and elevate moods. The theme of lyrics had some teachings of life, the beauty of nature, which helped them to keep fresh and gain knowledge. All the elements, i.e., expression through physical movements, lyrics/speech, and facial expressions interlinked, were carried out as expounded by scriptures (Ghosh, 2012). Relaxation was given at the end. Table 13 depicts the practices used for the intervention of canons of expression).

Table 13: Set of practices used for the intervention of canons of expression.

(Module is reviewed and appreciated by many veteran artistes across artistes community).

Practices	Duration	Scriptures	Reasons for selection
Warm up exercises	5 min		Flexing the joints and muscles.
Their miming on the various situations of their tough time with their impaired relative.	10 min		Enactment by the participants based on their previous negative experiences with their impaired relative to outburst frozen negative emotions.
Body movements (<i>āṅgika</i>) practice with musical notes with rhythm Movements of hands, neck, eyes, eyebrows, head, legs, shoulders etc. were be taught session by session).	15 min	<i>Nāṭyaśāstra</i> and <i>Abhinaya darpaṇa</i>	Knowledge on important usages, identify the beauty in their own limbs, to give physical fitness, come out of shyness and group awareness.
Easy steps with hand movements choreographed for them	15		Choreographed keeping the non-learners of dance in mind. These steps make them feel comfortable with the Indian aesthetic dance backed by elements of Indian classical dance and give fitness, gait, balance, stability and endurance.
Lyrics and expression of intense emotions needed for lyrics (<i>vācika, sattvika</i>)	10 min.	<i>Nāṭyaśāstra</i> a	Participants practice expression of emotions with lyrics set to musical notes and songs and dialogues.
Discussion on emotions mentioned in the lyrics	10 min.	Inspiring literatures	Discussion on aspects of classification of emotions, how it acts in different layers of mind and its evaluation to songs practiced.
Relaxation	10 min		
Total duration	75mins		

ii) Intervention of yoga

Yoga group participants were given loosening exercise (*shithila*), physical postures (*āsana*) in standing, sitting, supine and prone postures, breathing practices (*pranayama*), meditation, and instant and quick relaxation techniques in between. The yoga practice protocol is given in Table

7. Further, discussions on various topics relating to yoga and play of emotion and its self-resilience techniques based on yogic scripture followed by deep relaxation technique were introduced. The yoga program was designed by qualified yoga experts catering to the physical, emotional, and mental well-being of the caregivers, to help them deal with their needs effectively. The duration of practice was 75 minutes/day, thrice in a week. The adherence of the participants to the study was monitored by maintaining an attendance register. (Yoga module Table 14).

Table 14: Set of practices used for the intervention of yoga.

Name of the Yoga practice	Translation	Duration
Practical set I		
Sūksma vyayama	Loosening practices	5 mins
Hastavistāra śvasanam	Hand stretch breathing	1 min
ardhakati cakrāsana	Half-waist wheel posture	2 mins
Ardha cakrāsana	Half-moon posture	2 mins
Pāda hastāsana	Hand to feet posture	1 min
sūrya namaskāra	Sun salutation (6 rounds)	10 mins
	Instant Relaxation Technique	1 min
Marjāla usirāta	Cat breathing	1 min
Vajrāsana	Diamond posture	1 min
Śaśankāsana	Hare posture	1 min
Ardha uśtrāsana	Half camel posture	1 min
	Quick Relaxation Technique	2 mins
Uttanapāda śvasanam	Straight let raise breathing	1 min
Bhujangāsana	Serpent posture	1 min
Śalabhāsana	Locust posture	1 min
	Deep Relaxation Technique	5 mins
Kapālabhāthi	Breath of fire	2 mins
Nādiśuddhi	Cleansing Nādis (10 rounds)	7 mins
Śitali / śitkāri	Cooling breaths	
Omkara dhyāna	Om meditation (Imagery meditation)	10 mins
Satsang	Jnana yoga and Bhakti yoga (Topics on yoga philosophy, health.)	15 mins
	DRT	5 mins
	Total duration	75 mins

5.5 DATA EXTRACTION

On the first day the participants from all three Centers were gathered in a single place. There were randomized based on Zarit burden scale. Pre-post data relating to EPI parameters were collected before and after interventions by Bio well instrument to know the immediate effect of interventions. It helped to avoid humidity or temperature differences that can affect EPI parameters. Data collected on all psychological parameters were at pre (baseline), mid (at the end of 4th week) and post (at the end of 8th week) training. Concerning the EPI parameter, the baseline data were collected by reading from 10 fingers of each subject using EPI technology developed by Saint-Petersburg, Russia (GDV camera Pro with an analog video camera, model number: FTDI.13.6001.110310). There was a gap of 3 hours from any meal before data collection. All data were recorded as per the stipulated guidelines for EPI measurements that helped to maintain the reliability and reproducibility of the acquired data. Participants were guided to remove all metallic objects from their bodies 24 hours before data collection. Calibration of the equipment was carried out before acquiring data. Further, during data collection, participants were seated on an electrically isolated surface and placed their fingertip on the dielectric glass to capture the image. After each recording, the dielectric glass surface was cleaned by an alcoholic solution. Atmospheric temperature and humidity were monitored by Hygrometer (Equinox, EQ 310CTH), and it was maintained 26.8°C and 52.2%, respectively. Similarly, at post-intervention (at the end of 8th week), data of EPI parameters collected.

5.6 DATA ANALYSIS

The statistical analysis was using SPSS 21.0 (IBM Corp., Armonk, NY). The data were tested for normality that showed no significant difference in age, socioeconomic status, and Zarit burden scale. The repeated measures analysis of variance (ANOVA) was done with two factors, i.e., Groups (Dance, Yoga, and Control) and Levels (pre, mid, and post) for each outcome measures for psychological parameters. Repeated measures of ANOVA were carried out

separately, followed with Bonferroni correction, three times of all the assessments, and pre and post for EPI parameters. Pearson's correlation between self-reported scales was done for both groups. The statistically significant was considered at $p < 0.05$.

Concerning data analysis of EPI parameters, the captured EPI Images were loaded into the EPI software, and the coronal discharges corresponding to the organs and organ systems were exported into a spreadsheet. Each record had 82 variables (parameters) per subject. The parameters taken into account were: (a) *Activation Coefficient (AC)*: measure the level of stress and range between 0-2: absolutely calm and relaxed; 2-4: normal, calm condition; 4-6: excited state, characteristic of active work, emotional excitement, and tense activity; 6-7: Reaction to a previous stressful situation, heightened nervousness, accumulated during long term stress, emotional tension, and autonomic disorder; 7-10: very high-stress level, the peak of emotional excitement. b) *Communication energy (C)*: measures the total energy of communication for each organ system. The energy of 5 Joules is considered normal. A range of 4-6 is considered a normal zone. Less than 4 indicates weakness, and more than 6 indicates hyperactivity caused by an imbalance in the organ systems. In due course, the organ system tries to fix this imbalance naturally to bring back normal range. If it does not happen, the organ system gets weakened day by day. In this regard, a change of 0.5 Joules can pose the intervention as effective. (c) *Entropy (E)*: indicate the coherence of the energy. It means less entropy specifying more organized energy. (d) *Cakra*: 'cakra' means 'wheel of light.' Each *cakra* being psychic Centre of astral body represent nerve reflexes associated with group of functions as per their area of supply. It is related to both internal and external energy flow. In the study I) Value of *cakras*: indicates the amount of positive and negative energy flowing in that *cakra* and II) Symmetry of *cakra*: indicates the comparison of right and left halves of the *cakra*.