5.0 METHODOLOGY

5.1 PARTICIPANTS

5.1.1 Sample Size

Sample size was calculated by using G* power software version 3.0.10 from earlier study "Yoga Therapy Decreases Dyspnoea-Related Distress and Improves Functional Performance in People with Chronic Obstructive Pulmonary Disease: A Pilot Study" for the variable 6MWT (Donesky-Cuenco et al., 2009). A required sample size of n=72 (36+36) was obtained by applying Cohen's formula for effect size of 0.78 and an alpha of 0.05, powered at 0.9. (Appendix 1)

5.1.2 Inclusion Criteria

The inclusion criteria were as follows; non-smoking male coal miners aged 36 to 60 years, physician diagnosed COPD with spirometric evidence of chronic airflow limitation (FEV1/FVC, Post BD<0.70), Global initiative for Obstructive Lung Disease (GOLD, 2014) stage II and III COPD, clinically stable for at least 3 months; literate to complete the questionnaires, sufficient cognitive function to follow instructions for spirometry, able to walk without aid, willing to complete all study assessments, and provide informed consent.

5.1.3 Exclusion Criteria

Participants were excluded if any of the mentioned criteria were positive. Myocardial infarction, COPD exacerbation within last three weeks, recent surgery to thorax, abdomen, head, eyes or ears, unaccountable haemoptysis, severe hypertension, recurrent angina within the previous six months, hospitalization within 3 months, respiratory tract infection within one month of enrolment, basal BP > 180/100 mmHg, resting pulse rate > 120 bpm, Body Mass Index (BMI) > 35 kg/m2, previous involvement in yoga rehabilitation programs; recent

injury or neuromuscular conditions interfering with exercise tests; present and ex-smokers (smoking is a confounding variable).

5.1.4 Source of Participants

Patients visiting the out Patient Pulmonology Department of Central Hospital, Mahanadi Coalfields Limited, Rampur Colliery, Brajraj Nagar, Jharsuguda, Odisha.

5.1.5 Setting

The Yoga group learnt Yogic practices at the said Central Hospital, which has a spacious hall with a quiet atmosphere suitable for yoga practice.

5.1.6 Signed Informed Consent

Written information regarding the study was provided to all participants who volunteered for the study and signed informed consent was obtained from all participants after explaining the study in detail before the trial commenced.

5.1.7 Ethical Considerations

The study protocol was approved by the institution ethics committee (Swami Vivekananda Yoga University, Bangalore) through RES/IEC/28/2014. All procedures were performed according to the Declaration of Helsinki research ethics.

5.2 STUDY DESIGN

This is a randomized, waitlist control, single blind clinical trial in which participants were assigned to two groups (yoga and control). Of 279 coal miners screened, 162 failed at least one exclusion criterion; another 36 refused informed consent for the investigation; 81 signed up for the trial, but after 9 further dropouts (5 from yoga and 4 from control), final data were only available for 72 [Figure 3].

5.3 STUDY PROTOCOL

At enrolment, medical, exposure histories, pulmonary symptoms, information about current pharmacological treatments were obtained, and clinical examinations performed a specialist physician. Comorbid diagnoses were established from clinical histories and examination findings, supported by reviews of available medical records. The yoga group practiced a set of integrated yoga practices specially designed for COPD for 90 minutes daily, 6 days per week for 12 weeks. Participants of control group continued conventional therapy, completing all assessments at the same times as the yoga group; they were offered yoga at the end of the study. All participants were asked to refrain from participating in any other yoga classes during the study period.

5.4 RANDOMIZATION

Participants were randomized in to two groups using a computer generated random number table obtained from www.randomizer.org. Numbered opaque envelopes were used to implement the random allocation to conceal the sequence until interventions were assigned.

5.5 BLINDING AND MASKING

Double blinding is not considered possible for yoga interventions, where participants and trainer can recognize group assignment. However, giving and scoring the assessments were masked wherever feasible. The following were blind to the subjects' intervention group: the statistician who generated the randomization sequence and subsequently analysed the data; the clinical psychologist who administered and scored the psychological questionnaires; and the researcher who carried out allocation and assessments. The questionnaires' were coded and answer sheets were analysed only after completion of the study. Participants in yoga intervention group could not be blinded to treatment allocation arm due to the nature of the intervention.

5.6 INTERVENTION

The IAYT module was developed by SVYASA specifically for COPD based on its 30 years of research. It included simple and safe practices at physical, mental, intellectual, and emotional levels consisting of *asana*s, loosening exercises, breathing exercises, *pranayama*, cyclic medication, *yogic* counselling and lectures. IAYT aims to give a holistic treatment correcting imbalances at physical, mental, emotional and intellectual levels using various components like those listed above (Del, Villacres, Jagannathan, & Ramakrsihna, 2015). COPD special techniques were selected aiming for:

(a) Deeply relax different muscle groups.

(b) Slow the breath through breathing practices.

(c) Strengthen respiratory muscles.

(d) Calm the mind.

(e) Balance emotions - equipoise.

(f) Develop internal awareness and bliss in action.

Participants in the yoga group were given yoga training sessions for 90 minutes, 6 sessions a week for 12 weeks by trained yoga instructors. They were instructed to perform *asana*s in a relaxed state of mind, without superfluous power, in a smooth, harmonized, steadily controlled manner, being fully cognizant of the physical movements with well-coordinated breathing pattern. *Pranayama*s included both slow and fast breathing practices. Waitlist controls were offered the 12 weeks yoga program after the intervention period and post testing were complete. The detailed lists of practices are provided in Table 7.

Table: 7 Integrated Approach of Yoga Therapy for COPD used in this study.

Sl.	Name of the practices	Duration	Methodology	Benefits	Layer/ *kośa*
1	**BREATHING PRACTICES**	**10 Min.**	The movement of hands, legs, abdominal or thoracic muscles as needed in each exercise is synchronised with the breathing. For inhalation & exhalation, 'In' and 'out' instructions of the mind (or that of teacher) is used. Effort should be made to slow down the breathing gradually. Eyes will remain closed retaining the awareness throughout the practice.	Strengthen the respiratory muscles, develop the awareness of expansion and contraction of the airways, make breathing uniform, continuous and rhythmic, oxygenate all parts of the lung, opens out blocked air passages, stabilize effect on bronchial reactivity, and improve respiratory function.	*Prāṇamaya kośa* (Sheath of vital energy)
	Standing				
	Hands in and out breathing	1 Min.			
	Hands stretch breathing	1 Min.			
	Ankle stretch breathing	1 Min.			
	Sitting				
	Dog breathing	1 Min.			
	Rabbit breathing	1 Min.			
	Tiger breathing	1 Min.			
	Sasāṅkāsana breathing (moon pose)	1 Min.			
	Prone				
	Bhujaṅgāsana breathing	1 Min.			
	Śalabhāsana breathing	1Min.			
	Supine				
	Straight leg raising breathing	1 Min.			
2	**LOOSENING PRACTICES**	**10 Min.**	These are performed step wise with	Improve stamina in all muscles,	*Annamaya kośa*

			speed and repetitions which involve loosening of the joints, flexing of the spine. Attention during the practice is emphasized. The speed and number of repetitions should be increased depending on individual's capacity.	flexibility and tolerance to exercise, clears CO2, improve pulmonary function, respiratory pressures and overall cardio-respiratory fitness.	(Sheath of physical awareness)
	Forward and backward bending Side bending Twisting *Pawanmuktāsana kriyā* (Alternate leg) Rocking and Rolling *Surya Namaskāra* x 3 rounds	1 Min. 1 Min. 1 Min. 1 Min. x 2 1 Min. x 2 1 Min. x 3			
3	***YOGĀSANAS* (PHYSICAL POSTURES)**	**20 Min.**	*sthiram sukham āsanam // Yogāsanas* are firm and comfortable postures. The key aspects are relaxation of the body, slowness of mind and of awareness of breathing. *P.Y.S.2/46*	*yogaḥ citta vṛtti nirodhaḥ //* Mastery over the modifications of the mind, release mental tensions by dealing with physical level, revitalize and relax the body, calm down the mind. *P.Y.S.1/2*	*Annamaya kośa* (Sheath of physical awareness)
	Standing *Ardhakati cakrāsana* (Lateral arc pose) *Pādahastāsana* (Forward bend pose) *Ardha cakrāsana* (Half wheel pose)	2 Min. 2 Min. 2 Min.	Starting posture : *Tadāsana* Relaxation: *Śithila tadāsana*	Open up chest, improves stamina, increase confidence.	

	Sitting *Vakrāsana* (Twisting posture) *Ardhamatsyendrāsana* (Half spinal twist posture) *Paścimottānāsana* (Sleeping thunderbolt posture)	2 Min. 2 Min. 2 Min.	Starting posture : *Daṅdāsana* Relaxation: *Śithila daṅdāsana*	Improve flexibility of spine and strengthens thoracic, abdominal and limb muscles.	
	Prone *Bhujaṅgāsana* (Serpent pose) *Śalabhāsana* (Locust pose)	2 Min. 2 Min.	Starting posture : *Makarāsana* Relaxation: *Makarāsana*	Improve shoulder flexibility, stamina in thigh muscles, release stiffness, increase lung capacity, and promote expansion of rib cage.	
	Supine *Saravāṅgāsana* (Shoulder stand pose) *Matsyāsana* (Fish Pose)	2 Min. 2 Min.	Starting posture : *Śavāsana* Relaxation: *Śavāsana*	Invigorate all parts of the body, improve metabolic rate.	
4	***YOGĀ* CHAIR BREATHING**	**10 Min.**	This is a special eight stepped breathing technique developed by SVYASA found on the knowledge base to help in breaking the vicious cycles of anxiety and bronchospasm during acute attacks by deconditioning autonomic	Deep relaxation of respiratory muscles, opens up airway obstruction, overcomes the bronchospasm effectively, minimizes the acute episodes, improves confidence, and reduces panic anxiety.	*Prāṇamaya kośa* (Sheath of vital energy)
	a) Instant Relaxation Technique b) Neck muscle relaxation with chair support c) Neck movements in *Vajrāsana* *d)Sasāṅkāsana* movement e) Relaxation in *Tādāsana*	1 Min. 1 Min. 1 Min. 1 Min. 1 Min.			

	f) Neck movements in *Tādāsana* g) *Ardha cakrāsana - Pādahastāsana* h) Quick Relaxation Technique	1 Min. 1 Min. 3 Min.	arousal. The participants were asked to resort to this technique using a chair as a prop.		
5	***PRĀṆĀYĀMA***	**10 Min.**	*Tasminsati śvāsa praśvāsayor gati vicchedaḥ prāṇāyāmaḥ।* *After perfection of posture is* attained, *the movements of inhalation and exhalation are regulated by consciously breathing long, subtly and with counts while having attention on different parts of the body. P.Y.S. 2/49*	*prāṇāyāmenayuktena sarvarogakṣayo bhavet।* Improves balance of body mind complex, brings emotional stability through slowing down the mental and physical processes, decreases metabolic activity, activates parasympathetic state, and improves lung function parameters. *H.Y.P. 2/16*	*Prāṇamaya kośa* (Sheath of vital energy)
a)	*Kapālabhāti* (Frontal brain cleansing) (High frequency yoga breathing technique)	2 Min.	*Kapālabhāti* consists of a series of fast successive bursts of exhalations followed by automatic passive inhalations. It is performed rapidly like the bellows of a blacksmith.	*Kapālabhātirviklyātā kaphadoṣaviśoṣaṇī। H.Y.P 2/35* Strengthens diaphragm, cleanses lungs and entire respiratory tract, improves lung capacity, and increases tolerance of brain cells to	

				acid base imbalances in blood stream.	
b)	*Vibhāgiya prāṇāyāma* (Sectional breathing)	2 Min.	Preparatory practice having three sections; a) Abdominal, b) Thoracic, c) Clavicular breathing.	Increases vital capacity of the lungs, slows down the breath, and strengthens of all three groups of muscles of respiration.	
c)	*Nāḍīśodhana prāṇāyāma* (Alternate nostril breathing)	2 Min.	Sitting in *Padmāsana*, air should be inhaled through the left nostril after having retained the breath as long as possible, it should be exhaled through the right nostril, and again inhaled through right after performing *kumbhaka* and exhaled through the left nostril.	Opens up nostrils, clears the nasal passages, calms down the mind, helps in bronchial asthma, nasal allergy, bronchitis, brings reduction in stress and autonomic balance, increases PEFR, PP, decreases PR, RR, BP, increases parasympathetic activity.	
d)	*Ujjayi prāṇāyāma* (Diaphragmatic breathing)	2 Min.	With closed mouth, air should be inhaled deeply until the breath fills all the space between the throat down to the lungs with a hissing sound, after *kumbhaka* , air should be exhaled through the left nostril.	This removes phlegm in the throat and helps in diseases due to *kapha* like tonsillitis, sore throat, chronic cold, cough and bronchial asthma, lowers the oxygen consumption and metabolic rate.	
e)	*Bhrāmarī prāṇāyāma*	2 Min.	After quick inhalation air is exhaled	Relieves stress and cerebral	

	(Bee breathing)		slowly producing a soft humming sound.	tension, harmonize the mind, deals problems of sore throat, tonsils etc.	
6	**MEDITATION**	**10 Min.**	Meditation should be done in any comfortable meditative posture with spine erect and eyes closed. Consciously breath is slowed down allowing the mind to calm down.	Improves information processing in brain, reduces stress, decreases metabolic and respiration rate, calms down the mind.	*Manomaya kośa* (Sheath of mental activities)
a)	*Nādānusandhāna* (Alternate day)	10 Min.	Different sounds like A,U,M and AUM are chanted loudly so that they generate fine resonance all over the body.	Improves emotional equipoise, higher creativity, freshness, lightness, awareness and expansion.	
b)	Om Mediatation (Alternate day)	10 Min.	Sitting in any meditative posture "Om" is chanted mentally, not giving chance for distractions.	Achieves calmness, peace, serene, bliss, silence state of mind, improves concentration, memory, attention span.	

7	**DEEP RELAXATION TECHNIQUE (DRT)** in *Śavāsana* (corpse pose)	**10 Min.**	DRT is an eight step method developed by SVYASA DRT is an eight step method developed by SVYASA, practiced preferably lying down in savasana with eyes closed. This is done by taking a trip to different parts of the body from toes to head gradually with visualization, awareness and deeper feeling of relaxation.	Invigorates deep rest, decreases metabolic rate, reduces demand and stress, PR, RR, BP, muscle tension, oxygen consumption.	*Annamaya kośa* (Sheath of physical awareness)
8	**YOGIC COUNSELLING/ LECTURES**	**10 Min.**	Yoga counselling, lectures and interactions through questions and answers were essential for awareness of one's problems. It was conducted in a group and later one to one basis.	Helps to diagnose and remove the psychological conflicts of the individuals, enhances positive thinking and facilitates stress management.	*Vijnānamaya kośa* (Sheath of self knowledge)
	Yoga philosophy and health, *Pancakoṣa viveka*, Lifestyle modification, Emotion and coping, Diet and exercise, COPD causes, complications and lifestyle factors, Stress reaction and its management.				
9	***KRIYĀ* (once a week)**	**90 Min.**	To cleanse the inner tracts, thereby developing involuntary control over voluntary reflexes.	Develops inner awareness; desensitizes hypersensitive reactions in the pathways.	*Annamaya kośa* (Sheath of physical awareness)
	Theory on *kriyā*	10 Min.	The procedure is explained with the help of diagrams prior to the	Provides knowledge on procedure, benefits and limitations of each	

			practice.	*kriyā*.	
	Jala Neti	20 Min.	Lukewarm saline water is inserted through one nostril with a special *neti* pot and allowed to flow through the other nostril.	*kaphadoṣā vinaśyanti* । *G.S 1/51* Destroys the disorders of phlegm. Clears nasal passages, sinusitis bronchitis and hypersensitivity	
	Sutra Neti	20 Min.	Blunt soft rubber catheter is gently pushed through nose and pulled out through mouth massaging the nasal passage.	Mastery over involuntary reflexes of sneezing and cough, desensitize to dust and pollution, relieves in nasal allergy.	
	Vamana Dhouti	25 Min.	Stomach is filled with warm saline water until one feels like vomiting. By pressing middle three fingers of the right hand on the root of the tongue vomiting sensation is stimulated until all water comes out.	*kāsaśvāsaplihakuṣṭani kapharogāśca viṁśatiḥ* । *dhautikarmaprabhāvena prayāntyeva* na *saṁśayaḥ* । Clears the air passages through reflex stimulation, useful for asthma and bronchitis. *H.Y.P. 2/25*	
	Deep Relaxation Technique (DRT)	15 Min.	DRT was given by eight step method of SVYASA.	Invigorates deep rest, decreases HR, RR, BP, muscle tension, oxygen consumption.	

5.7ASSESSMENTS

Assessments were made on both groups at baseline and after 12 weeks of intervention.

5.7.1 PRIMARY VARIABLES

5.7.1.1 Pulmonary Function Test (PFT)

Spirometry provides an objective assessment of airflow obstruction which includes tests of pulmonary mechanics; FVC, FEV1, FEV1/FVC and FEF. The measurements of the amount (volume) and/or speed (flow) of air that can be inhaled and exhaled are used to identify airway obstructions in following conditions such as: asthma, pulmonary fibrosis, cystic fibrosis, and chronic obstructive pulmonary disease and to diagnose bronchial hyperresponsiveness to exercise or pharmaceutical agents. The PFT were determined by using a computerized spirometer (Spirovit, Switzerland), before and after the yoga training. The same equipment was used to test all participants.

Procedure

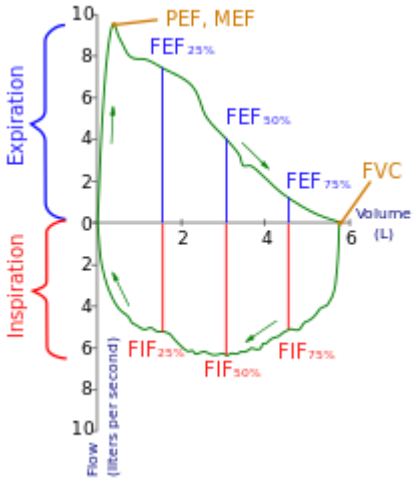
The participants were familiarized with the set up and detailed instructions and demonstrations were given for our satisfaction. The participants were made to breathe out forcefully, following deep inspiration, into the mouthpiece which was attached to the pneumatachometer. The expiration was maintained for a minimum period of 8 seconds. Three satisfactory efforts were recorded according to the norms given by American thoracic society and only the highest reading was taken for data processing. All tests were carried out at the same time of the day, between 9 am to 11 am, to avoid the possible variations, because rhythmic changes in the physiological functions were found to be associated with changes in the performance during this period. The tests were done in a quiet room in order to alleviate the emotional and psychological stresses. During the tests, a maximum effort from the participant was ensured by adequately motivating them to perform at their optimum level.

The manoeuvre is highly dependent on patient cooperation and effort. The pulmonary mechanics were repeated three times to ensure reproducibility and the best trial was reported.

The following mechanics were recorded;

• **Forced Vital Capacity (FVC):** It is the maximum volume of air that can be exhaled after full inspiration during a forced manoeuvre, measured in liters. It is the most basic manoeuvre in spirometry tests.

• **Forced Expired Volume in one second (FEV1):** It is the volume of air that can forcibly be expired in the first second of maximal expiration after full inspiration. This is a measure of how quickly the lungs can be emptied. FEV1 is influenced by the age, sex, height, mass and ethnicity, and is best considered as a percentage of the predicted normal value.



• **FEV1/FVC ratio:** It is the ratio of FEV_1 to FVC i.e. FEV1 expressed as a percentage of the FVC, gives a clinically useful index of airflow limitation. In healthy adults this should be approximately 70–80% (declining with age). The ratio FEV1/FVC less than 70% indicates airflow limitation and the possibility of COPD. In obstructive diseases (asthma, COPD, chronic bronchitis, emphysema) FEV_1 is diminished because of increased airway resistance to expiratory flow; the FVC may be decreased as well, due to the premature closure of airway in expiration, just not in the same proportion as FEV_1. In restrictive diseases (such as pulmonary fibrosis) the FEV_1 and FVC are both reduced proportionally and the value may be normal or even increased as a result of decreased lung compliance.

- **Forced expiratory flow (FEF) -** It is the flow (or speed) of air coming out of the lung during the middle portion of a forced expiration. FEF 25–75% is the mean FEF between 25% and

75% of the FVC, has also been known as the maximum mid-expiratory flow. This index is taken from the blow with the largest sum of FEV1 and FVC.

5.7.1.2 COPD Assessment Test (CAT)

CAT is a short questionnaire developed for assessing and monitoring COPD in routine clinical practice. It provides a valid, reliable and standardized measure of the impact of COPD on a patient's health and well being (Jones et al., 2009, 2011). It consists of eight items rated using a Likert-type scale of 0–5, providing a score out of 40, higher scores representing poorer quality of life. Despite the small number of items, it covers a broad range of effects on patients' health. It takes less time to complete than other health related QoL questionnaires (Ringbaek, Martinez, & Lange, 2012). CAT is sensitive to changes in disease progression over time and to the effectiveness of treatments (Dodd et al., 2011; Mackay et al., 2012). Internal consistency is excellent with Cronbach's $\alpha = 0.88$ and test-retest reliability good in stable patients (ICCC=0.8) (Jones et al., 2009).

5.7.1.3 Peak Expiratory Flow Rate (PEFR)

PEFR is the highest forced expiratory flow that can be generated during forced expiratory maneuver measured with a standard Wright Peak Flow Meter. The subjects were informed to blow Fast Hard Blast until they had emptied out nearly all of the air from their lungs. The participants were familiarized with the set up and detailed procedure was explained to them in local language. All tests were carried out at the same time of the day, between 8 am to 11 am, to avoid diurnal variations. It was measured three times and the best trial was reported.

5.7.1.4 Six minute walk test (6MWT)

This was performed, according to American Thoracic Society guidelines (Crapo et al., 2002). As an objective measurement of true functional capacity, the 6MWT is usually better than self-reports or questionnaires to overcome over- or under-estimation. For patients with COPD

it is a good indicator of exercise capacity, and also reflects an individual's sub-maximal level of functional capacity to perform activities of daily living. In clinical practice, it is commonly used for defining the severity and clinical course of the disease, in order to plan the best treatment possible and after a therapeutic intervention to evaluate improvement of responses, both symptomatic (dyspnoea and fatigue) and physiological (distance walked, peripheral capillary oxygen saturation, and pulse rate) (Vilaró, Resqueti, & Fregonezi, 2008).

Participants were asked to walk back and forth at their own pace in a flat, straight, hard surfaced 35 m corridor, and to try to cover as much distance as possible in the time allotted. Rest stops were permitted during the test, but they were instructed to resume walking as soon as possible. Standardized phrases were used at each minute (e.g. “You are doing fine. Five minutes to go.”, “Keep up the rhythm. Four minutes to go.”, “You are doing fine. You are halfway to the end.”, “Keep up the rhythm. Only two minutes to go.”, “You are doing fine. Only one minute to go.”).Total distance covered was recorded.

5.7.1.5 Dyspnoea

Participants were asked to rate their subjective scores of “shortness of breath” on cessation of the 6MWT using the modified Borg scale on a score of 0-10. This consists of a vertical number scale ranging from 0 (none) to 10 (maximal), with corresponding verbal expressions of magnitude of breathing difficulty. Higher scores indicate worse dyspnoea.

5.7.1.6 Fatigue

Participants are asked to rate their degree of fatigue on a vertical modified Borg’s scale labelled 0 to 10, with 0 at the top indicating “nil” fatigue and “10” at the bottom representing “worst possible experience of fatigue”. The scores were noted before and after the intervention.

5.7.1.7 Pulse oximetry

Pulse oximetry is a non-invasive method affording rapid measurement of oxygenation of haemoglobin in peripheral capillary (Schermer et al., 2009). Post exercise peripheral capillary oxygen saturation (SpO_2%) and pulse rate were assessed for every participant using a portable pulse-oximetry device (Nonin 9570 LED pulse oximeter, USA). Percentage of peripheral capillary oxygen saturation was measured after connecting the optical diodes on the patients' fingers by trans-cutaneous pulse oximetry. Each experiment was performed three times and mean values recorded. None had a baseline SpO_2 less than 88% or received domiciliary oxygen therapy.

5.7.2 SECONDARY VARIABLES

5.7.2.1Beck Depression Inventory II (BDI-II)

All participants completed the BDI, 2nd edition (Beck, Steer, & Brown, 1996). BDI-II is a self-report questionnaire of 21-items scored from 0 to 3. It is designed to assess depressive symptoms experienced within the previous two weeks. It has high internal consistency (Cronbach's $\alpha = 0.92$); mean test-retest reliability is 0.72 (Dozois & Covin, 2004). BDI-II scores range from 0 to 63, with categorical depression ratings of "minimal" (0–13), "mild" (14–19), "moderate" (20–28), and "severe" (29–63). BDI is considered a valid measure of depressed mood for diverse populations.

5.7.2.2 State Trait Anxiety Inventory (STAI)

STAI is a reliable, valid and widely used measure of anxiety for clinical practice and research, with a high degree of internal consistency (Spielberger, Gorsuch, & Lushene, 1970). Cronbach's α is 0.85 for the total scores (Vitasari, Wahab, Herawan, Othman, & Sinnadurai, 2011). It includes separate measures of state anxiety and trait anxiety each comprising 20 items rated on a 4 point scale from 0 to 3 which range from 20, minimum, to

80, maximum. Form S evaluates state anxiety, how subjects feel ‘at this moment’; while Form T assesses trait anxiety, how the respondent feels ‘most of the time’. In India its reliability and validity are well established following extensive use in adult populations. State anxiety reflects subjective and transitory emotional states characterized by consciously perceived feelings of nervousness, tension, worries and apprehension, and heightened autonomic nervous system activity. In contrast, trait anxiety refers to relatively stable individual differences in anxiety proneness as a personality attribute that denotes general tendency to respond with anxiety to perceived threats in the environment.

5.7.2.3 Pittsburg Sleep Quality Index (PSQI)

PSQI is a psychometrically validated, self-reported, effective instrument used to assess the quality and patterns of sleep in the older adult over the last month (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). Nineteen individual items were recoded to comprise seven sleep components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction, each of which has a range of 0-3 points, whereby 3 reflects the negative extreme on the Likert Scale. The sum of scores for these seven components yields one global PSQI score, ranging between 0-21. A global sum of “5”or greater indicates a “poor” sleeper, having sensitivity of 98.7 and specificity of 84.4 as a marker for sleep disturbances. PSQI has internal consistency (Cronbach's alpha) 0.80 (Carpenter & Andrykowski, 1998) and test-retest reliability 0.87 (Backhaus, Junghanns, Broocks, Riemann, & Hohagen, 2002). The global sleep quality score was the primary outcome and the subscale scores of global sleep quality characteristics were secondary end.

5.7.2.4 Numerical Rating Scale (NRS)

Pain intensity was measured on an 11-point numerical pain rating scale, prepared for the purpose by drawing a horizontal 10 cm line in the centre of a white sheet with '0' as nil pain and '10' as worst possible pain (Farrar, Young, LaMoreaux, Werth, & Poole, 2001). Separate sheets were used at each assessment time. Participants were asked to indicate the pain intensity by a dot on the line.

5.7.2.5 Autonomic variables

Status of autonomic function was assessed by cardio respiratory parameters (BP, HR and RR).

- **Blood Pressure (mm of Hg):** The participants were asked to sit in relaxed position and BP was measured on the right arm in sitting position using a standardised mercury sphygmomanometer (Diamond Company, India).
- **Heart rate (Beats per minutes):** The number of beats per minute of the pulse was noted manually at the radial artery of the right hand by using a stopwatch while the person was in sitting position.
- **Respiration rate (RR cycle per minutes):** The resting respiration rate was noted by visual observation of the respiratory movements of the abdomen or the chest wall while the participant was seated. To ensure that the RR was recorded when the person was not aware of his breathing; the therapist was trained to note the RR by visual observation while he continued to keep the fingers on the radial artery so that the participant's attention could be diverted.