CHAPTER V

METHODOLOGY OF EXPERIMENTAL RESEARCH

This chapter presents the details about subjects, design, outcome variables, Intervention of the two groups, Data extraction, and Data Analysis.

5.1 Subjects

The first 80 CLBP patients admitted between April 2005 and June 2006, who satisfied the selection criteria, were recruited as subjects for the study (in all 160 CLBP patients were admitted in this time period).

5.1.1 Sample size

Sample Size was calculated as follows using G power Software. The effect size was calculated by the Cohen formula, using the means and standard deviations of an earlier interventional study on 120 subjects funded by the Central Council for Research in Yoga And Naturopathy – Ministry of Health and Family Welfare, Government of India (not published in indexed journals). For these calculations we used the noncommercial statistical power analysis program G*Power (Faul, 2007). In our earlier funded project study we had reported the following values. The mean± SD before for the variable spinal flexion) was 61.68 ±19.20 and after the intervention it increased to 74.88 ± 13.20 with a difference of means of 16.57. The Effect Size of that study was 0.896. A sample size of 36 for one arm (36x2 = 72) was obtained by feeding this value of 0.89 (from the earlier funded study) as the effect size, an alpha value of 0.05 powered at 0.95. The sample size that was actually recruited was 80 subjects. The effect size of spinal flexion in this study is 1.30 in the yoga group 1st week.

5.1.2 Source of subjects: Patients who were admitted to the Yoga therapy residential Health Home (Ārogyadhāma) at Prashanti Kutiram, Bangalore.
5.1.3 Setting: SVYASA’s health centre is situated in its Prashanti Kutiram Campus, set in countryside, 35 kms south of Bangalore, India. It has a quiet atmosphere.

5.1.4 Selection Criteria

5.1.4.1 Inclusion Criteria

(a) History of CLBP of more than 3 months

(b) Pain in lumbar spine with or without radiation to legs (Spitzer et al 2007)

(c) Age: 18 to 60 years.

5.1.4.2 Exclusion Criteria

(a) Organic spinal pathology such as malignancy (primary or secondary), or chronic infection confirmed by X-ray

(b) Recommended surgical intervention

(c) Severe obesity

(d) Critically ill.

5.2 Medical Assessment

Initial assessment was conducted by a rheumatologist. Two experts (radiologist and orthopaedic surgeon) gave their opinion on whether anteroposterior and lateral Rontgenographic pictures of the lumbar spine satisfied the selection criteria. A semi-structured interview was used to obtain both demographic and vital clinical data, including personal, family and stress history.

5.3 Design of the study

It was a randomized crossover control study. The experimental group received yoga therapy and yoga-based lifestyle change program along with routine medical management
whereas the control group was given healthy lifestyle change intervention with medical treatment. Every patient who is a part of this study under-went both the interventions.

I) Yoga therapy- based lifestyle change intervention (YLSP)

II) Healthy lifestyle change (exercise based) intervention (ELSP)

*Fig:5.1*

5.4 Randomization

Two groups of 40 numbers the spanning integers 1 to 80 were created by a computer generated random number table from www.randomizer.org. As CLBP patients were admitted to the Health Centre week by week, they were sequentially assigned to one of the two groups so generated. To conceal the sequence until interventions were assigned, numbered containers were used to implement the random allocation.
5.5 Blinding and Masking

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’ coded answer sheets were analysed only after completion of the study. Double blinding is not possible in intervention studies.

5.6 Ethical clearance and consent

The study was cleared by the institutional review board and the ethical committee of the institution. Signed informed consent of the patients was obtained. The consent form had clear instructions about the randomized allotment to either of the interventions to start with followed by shifting to the other intervention in the second week. The utility of the control session as a conventionally accepted therapeutic regime (not as a placebo waiting period) was clarified so that they could participate in both the interventions with equal degree of motivation.

5.7 Credibility

To ensure that the subjects would see that both interventions had comparable credibility, subjects were informed that they would be instructed in one of the two well accepted therapeutic modules in the week, yoga or a standard physiotherapy physical exercise regime used for CLBP treatment. Subjects were in no way given the impression that either module was a ‘placebo waiting period’.

5.8 Variables

5.8.1 Semi-Structured Interview Schedule

This was developed for the present study to obtain demographic details like clinical data, personal and family history. The information was collected under the following sections:
Table 5.1  Semi-Structured Interview Schedule

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>a)</td>
<td>Socio-demographic details: Information regarding name, age, sex, occupation and marital status was obtained.</td>
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<tr>
<td>b)</td>
<td>Clinical History</td>
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<td>c)</td>
<td>Past History:</td>
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<td>d)</td>
<td>Family history:</td>
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<td>e)</td>
<td>Personal History</td>
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<td>f)</td>
<td>Stress History: Past and present</td>
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<td>g)</td>
<td>Examination: Height, weight, Blood pressure, pulse rate, Respiratory rate, cardiovascular system, respiratory system gastrointestinal system, nervous system, Spine, SLR, right &amp; left. Tenderness- Para spinal, spine, sacroiliac joints and others.</td>
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<td>h)</td>
<td>Investigations: X-ray, MRI and others.</td>
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<tr>
<td>i)</td>
<td>Observations during the interview.</td>
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<tr>
<td>g)</td>
<td>Any other relevant information.</td>
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**Table 5.2 Clinical Variables**

1. Measures of Disability and pain.
   - Oswestry Disability Index.
   - Oswestry Disability Index. ODI - Section 1 (Measure of Pain).
   - Numerical Rating Scale for pain. (NRS).

2. Objective Measures of Spinal Mobility.
   - Sit and Reach (SAR)
   - Straight Leg Raising (SLR) test
   - Spinal flexibility using a dial type goniometer.

3. Psychological Variables.
   - Oswestry Disability Questionnaire (ODI)
   - State –Trait Anxiety Inventory (STAI).
   - Beck Depression Inventory (BDI)
   - WHO Quality of Life Scale – Brief Version (WHOQOL – BREF)
   - Perceived Stress Scale.

4. General clinical variables
   - Blood pressure,
   - Pulse Rate,
   - Respiratory Rate,
   - Breath-Holding Time,
   - Height,
   - Weight,
   - X-Ray of Lumbar Spine AP & Lateral view, and
   - Symptom Score (SS).
5.8.3 Disability and Pain Measures

5.8.3.1 Oswestry Disability Questionnaire.

Functional Disability Index.

The Oswestry Low back pain Disability Index (ODI), a self administered questionnaire, developed by Jones and Hunt, England (Fairbank, 2000) was used to measure the disability. It has 5 graded questions for assessing the degree of pain in 10 different areas of living such as walking, standing, social life etc. Total score for ODI ranges from 0 to 100. The scores for each of the 10 sections of ODI are added and the final score is expressed as ‘percent disability’. Grading of the disability is described as follows:

(i) Minimal disability: (0% to 20%) when patient can cope with most living activities;
(ii) Moderate disability: (21% to 40%) when patient may be disabled from work and reports more pain and difficulty with sitting, lifting and standing;
(iii) Severe disability: (41% to 60%) when pain remains the main problem;
(iv) Crippled: (61% to 80%) pain affects all aspects of the patient’s life, and
(v) Bed bound or exaggerating (81% to 100%).

5.8.3.2 Numerical Rating Scale for pain (NRS)

This is considered to be a simple & reliable tool to measure subjective pain. It consists of a horizontal straight line of 10 centimeters marked on a clean white sheet. One end of the line marked 0 represents ‘No pain’ and the other end marked 10 represents ‘Worst possible pain’. The subject is asked to indicate his pain by marking a dot on this line.

5.8.4 Objective Measures of Spinal Mobility

5.8.4.1 Sit and Reach (SAR)

The sit-and-reach test was developed to measure hamstring and lower back flexibility and was first described by Wells and Dillon in 1952. To determine criterion-related evidence
for the sit-and-reach test as a measure of hamstring and lower back flexibility, test scores must be related to criterion measures. Jackson and Baker 1986 reported a moderate correlation (r = .64) between the sit-and-reach test and hamstring flexibility (Lemmink Koen, 2003).

This instrument is used to measure spinal flexibility. The subject sits on the floor with his legs extended towards the Sit and Reach apparatus touching it. He then bends forward to his maximum capacity pushing the indicator with his fingers keeping the elbows remains straight. The distance covered is then measured in centimeters.

### 5.8.4.2 Straight Leg Raising (SLR) test

**Straight Leg Raising (SLR) test**

A goniometer (Anand Agencies, Pune) that has two scales fixed at one end to a compass (calibrated in degrees), was used to measure SLR. The patient lies down on his back; the examiner stands on the right side of the couch, the goniometer is placed along the right leg on the couch with the centre of the compass supported firmly. Then the right leg is raised passively without bending the knee until the patient starts getting pain. The outer scale of the goniometer is then moved up along this leg and the angle between the two scales is read on the compass. Same procedure is repeated on the left side by the examiner moving over to the left side of the couch.

### 5.8.4.3 Spinal flexibility using a dial type goniometer

Spinal mobility is measured using a dial type goniometer (Anand Agencies, Pune). This instrument has a dial with calibrations from 0 degrees to 360 degrees. The instrument has a lock which can be used to lock the dial once the calibration is made. The measurements are taken for right lateral bending left lateral bending, forward bending and backward bending.
5.8.5 Psychological Variables

5.8.5.1 State –Trait Anxiety Inventory (STAI)

STAI developed by Spielberger et al (1970) consists of 2 forms (Y1 and Y2) each comprising of 20 items rated on a 4 point scale.

Form Y1 assesses state anxiety, defined as ‘a transitory emotional state that varies in intensity, fluctuates over time and is characterized by feelings of tension and apprehension and by heightened activity of the autonomic nervous system’ (Spielberger, 1970). It evaluates how the respondents feel right now at this moment.

Form Y2 evaluates trait anxiety, which is ‘a relatively stable individual predisposition to respond to situations perceived as threatening’ (Spielberger, 1970).

The overall median alpha co-efficient is 0.92 and the tool has adequate concurrent, convergent, divergent and construct validity (Spielberger et al; 1970). It has been extensively used in the Indian context and found to be useful.

5.8.5.2. Beck Depression Inventory (BDI)

This 21 item inventory devised by Beck et al,(1961) measures cognitive, affective and vegetative symptoms of depression. It assesses severity of both symptoms and attitudes specific to depressed individuals. The score for each item ranges from 0-3 and the range of total score is 0-63. A score between;

- 0-9: No depression
- 10-19: Mild depression
- 20-25: Moderate depression
- 26 +: Severe depression.
Reliability co-efficient for the BDI include correlation between each item and the total score ranging from 0.31- 0.68, and split half reliability ranging from 0.86 – 0.93 (Beck, 1988).

5.8.5.3 Perceived Stress Scale
The Perceived Stress Scale (PSS) has adequate internal test and retest reliability is correlated in the expected manner with a range of self-report and behavioral criteria. Earlier studies show that the relationships between PSS and the validity criteria were unaffected by age and sex (Cohen, et al. 1983). It was used for assessing baseline stress scores.

5.8.5.4 WHO Quality of Life Scale – Brief Version (WHOQOL – BREF)
The WHOQOL – BREF developed by WHO (1996), is a shorter version of WHOQOL-100 comprising of 26 items. The scale provides a measure of an individual’s perception of quality of life for the 4 domains: 1) Physical health (7 items) 2) Psychological (6 items) 3) Social relationships (3 items) and 4) Environment (8 items). The internal consistency of WHOQOL – BREF as determined by Chronbach’s alpha co-efficient ranges from 0.66-0.87. The scale is found to have good discriminant validity. (The WHOQOL Group, 1998). The domain scores are scaled in a positive direction (i.e., higher scores denote higher quality of life).

5.8.6 General Clinical Variables.

5.8.6.1 Blood Pressure (mm of Hg): B.P was measured daily in the afternoon at 3 pm by the same therapist on the right arm in sitting position using a mercury sphygmomanometer (Diamond Company, India).
5.8.6.2 *Pulse 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.

5.8.6.3 *Respiration rate:* The resting respiration rate (RR cycle per minutes) 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.

5.8.6.4 *Bhāmaré Time (BHT in seconds):*

The bhāmaré time measurement was designed to get a clinical measure of the ability of the person to prolong the expiratory rate on effort similar to slow vital capacity. Yoga texts indicate that voluntary slowing down of the rate of breathing and exhalation time are important indicators of the ability of the person to the reduce the perturbations of the mind. (*cale vāte cale chittam – hańa yoga pradēpika*- If the mind moves the breath moves and vice versa). This is similar to what is known in modern science to day that RR, PR and BP are simple but direct indicators of the state of autonomic arousal. Hence the bhāmaré time measurement was designed to get a measure of the exhalation time. Participant was asked to sit comfortably, take a deep breath in and start breathing out slowly to produce a low pitched humming sound (called bhāmaré in yoga) as long as long as he/ she can. The duration of this chanting was measured using a stop watch. The mean of the three consecutive attempts was noted as BHT in seconds.
5.8.6.5 **Weight:** It was measured by using the same weighing instrument on day one and day seven and day fourteen.

5.8.6.6 **Symptom Score (SS)**

A symptom check list was prepared for the study and –they were scored on a 4 point scale (0-3).

### 5.9 Intervention

#### 5.9.1 Yoga intervention

*Patāḷ jali* defines in his second aphorism ‘*yogāù citta vr̥tti nirodhaù*’ ([P.Y.S: 1.2](#)) that Yoga is a process of gaining control over the mind by cessation of the modifications of mind. By so controlling the mind one can reach the causal state. ‘*Tāda draṇāù svarūpe avasthānam*’ ([P.Y.S:1.3](#)). Then the Seer establishes himself in his original state. This technique of ‘mind control’ prescribed by *Patāḷ jali* has tools to develop the power of concentration and focusing of mind with increased speed of thoughts and to harness our power to stop all the thoughts in the mind. Another yoga master *Vasīṭha* emphasizes this aspect by defining yoga as *manaù praçamanopāyaù yoga ityabhidhēyate | | yo vā. 3.9.32 | |* which means Yoga is called a skilful trick to calm down the mind.

#### 5.9.2 Techniques of yoga

There are many methods of yoga catering to the needs of people in all walks of life in society to bring about the transformation of the individual. They are broadly classified into four streams. Swami Vivekananda puts them as work and worship, philosophy and psychic control.
1. Karma Yoga: This path of working in relaxation involves doing action with an attitude of detachment to fruits of action. This makes man release himself from the strong attachments and thereby brings in him a steadiness of mind which verily is Yoga-‘Samatvaà yogaù Ucyaте’.

Instruments of action and understanding (Karmendriyas and Jïänendriyas) get cleansed.

2. Bhakti Yoga: The control of emotions is the key in the path of worship that involves pure love to the Divine and is characterized by total surrender. In this modern world, man is tossed up and down due to emotional onslaughts. The path of Bhakti is a boon to gain control over emotional instabilities by properly harnessing the energy involved in it.

3. Jïäna Yoga: The present age of science has made man a rational being. Intellectual sharpness is imminent. Analysis forms the tool. The path of philosophy (Jïäna Yoga) is apt for the keen intellectuals and is centered around the analysis of ‘happiness’, the vital contribution of Upanıṣads. Also many other fundamental questions regarding the mind, the outside and inside world and the reality are taken up. Basic questions are raised even involving the intellect itself to reach the very basis of intellect.

4. Rāja Yoga: Culturing of mind is the key for success in almost all endeavors in our lives. This Yoga of ‘mind culture or psychic control (Rāja Yoga) gives a practical and easy approach to reach higher states of consciousness. It is based on the Amūga Yoga (Eight limbed yoga consisting of Yama, Niyama, Āsana, Prāēāyāma, Pratyahara, Dhāranā, Dhyāna and Samādhi) of Patājali’s yoga system (Nagendra et al 1998).
5.9.3 Concept of health and yoga

According to the World Health Organization (WHO) the state of Health is defined as a state of complete physical, mental and social well-being and not merely an absence of disease or infirmity. WHO also suggests a fourth dimension spiritual wellbeing. It is clear from this definition that health and ill-health are not two discrete entities as commonly understood but health should be conceived as a continuous function indicating the state of well-being. In the diagram, the 3rd quadrant ‘the region of ill-health’ represents what normally we designate as ‘Sickness’. Below this, man acts instinctively and is akin to animal man. Coming to the first quadrant, the region of ‘Normal Man’ the state of normal health is indicated. As he moves along the line further up, he becomes healthier featured by the dormant faculties expressing more vividly in man. This is shown as the region of Superman. In this state, the limitations of normal man namely the strong urges of thirst, hunger, fear and sex are reduced greatly and are fully under control.

Yoga is a systemic conscious process for accelerating the growth of a human being from his animal level and ultimately to divinity. It is a systematic methodology for an all round personality development-physical, mental, intellectual, emotional and spiritual components-of man. Thus, in its general methodology for the growth of man to divine
heights includes techniques useful for therapeutic applications in making man healthier. Yoga is a process for elevating oneself through calming of mind.

5.9.4 Yoga therapy

Yoga therapy techniques correct the problem from the most fundamental level. The corrections are sought from the innermost causal layer of our existence (Ānandamaya kośa or the soul or the master of the system). A total correction of the bodily disturbances is brought about by correcting the disturbances at the emotional, psychological and the vital energy levels. The integrated approach uses several techniques with an unique aim of reaching a state of silence or calmness of mind or deep relaxation and rest.

1. Yoga is a method to turn the mind inwards and achieve deep awareness of functions of internal organs. Internal awareness helps to solve one’s own internal psychological and emotional conflicts as in psychotherapy.

2. The internal awareness helps to change the learnt conditioning and helps to change the pattern of psychological and physiological responses as in behavior therapy.

3. Yoga is a technique of unfolding the potential divinity within, so that the dormant capabilities are opened up consciously. Just like in hypnotherapy, every man can tap his dormant capacities or alter his own physiology under the effect of a simple suggestion. Through yoga one does this consciously with self-mastery over such states of consciousness.

4. Yoga corrects the alterations in the Prāēa flow by slowing down the Prāēic activity gently and cautiously through conscious, slow, rhythmic breathing.

5. At the physical level, yogasanas enhance local relaxation and improves tolerance.
6. *Kriyās* may help in developing tolerance to external agents, similar to desensitization therapy for allergens.

The concepts to evolve the specific module of ‘Integrated approach of Yoga therapy (IAYT) for back pain were taken from traditional yoga scriptures (*Pātañjali* yoga Sūtras, *Upaniṣads and Yoga Vāsiṣṭha*) that highlight a holistic approach to health management at physical, mental, emotional and intellectual levels (Nagarathna & Nagendra, 2000).

**Om meditation:** In this meditation the syllable Om is used to achieve a state of alert-full rest (Telles, Nagarathna & Nagendra, 1995). The person seated in any comfortable meditative posture goes on repeating the syllable OM mentally leading to effortless flow of a single thought in the mind (*Tatra pratyayaikatānatā dhyānām*- *PYS*: 3.2) for ten minutes.

**Yoga-based special technique:** The yogic physical practices (back pain special techniques, Appendix 1) progressed from initial safe movements to final yoga postures. They included practices (a) to relax the spinal muscles through stretch as in I-5, 6 and by deep rest through breath awareness as in III and conscious guided relaxation of all parts of the body as in VI; (b) traction effect as in I-1, IV-1, 2, V-1, 2 and 3; (c) strengthening the back muscles as in I-4 and II-1, 2; (d) strengthening the abdominals as in I-1, 2, and 3. Safety of the practices was ensured by consultation with a senior physiatrist. Special care was taken to avoid acute forward or backward movements and jerky movements of the spine while designing the module (Nagarathna & Nagendra 2001).

**Yogic hymns:** Guided chanting (with meaning) of verses from *Bhagavadgītā* (the most popular Indian scripture) that describes the definition, and the streams of yoga to arrive
the concept of lifestyle change through self-mastery, self-surrender, self-analysis, and awareness in action.

**Lectures:** These were tailor-made to give the entire philosophical model through self-corrective techniques for healing. They included talks on the yogic approach to health and physiological effects of different yoga practices taught to them. There were talks on the concept of body mind and disease according to yoga, concept of inner core personality as the source of the healer within (Ānandamaya kośa), concept of how stress is understood in modern science and yogic definition of stress, understanding of how to use introspective correction of the responses to situations and people around, yogic concept of holistic health at physical, mental emotional, social and spiritual levels. Research done of the physiological effects of different yoga practices that help in the management of back pain.

**Deep relaxation technique:** This is a guided-relaxation technique that lasts for 10 minutes and is done in 3 phases of (i) relaxation from the tip of the toes to the head mentioning each part of the body specifically; (ii) letting the body ‘collapse’ on the ground with a feeling of ‘letting go’, chanting OM; (iii) feeling of expansion through visualization of the limitless sky or ocean (Vempati & Telles, 2002).

**Prāēāyāma:** Prāēāyāma is a state of voluntarily regulated breathing while the mind is directed to the flow of breath or Prāēa. A typical cycle of the slow type Prāēāyāmic breathing involves the phases of inhalation, exhalation; there are different kinds of Prāēāyāmas varying according to the durations of the phases in the breathing cycles, and the nostrils used. Yogic breathing practices were included to bring about a slow rhythmic breathing pattern to reduce the breath rate with internal awareness of the touch of the flow
of air through the air passages, which is an effective way to get mastery over the mind (Nagendra, 2000).

**Divine hymns:** Divine hymns sessions of singing were meant to replace suppressed emotions and open up the gentle emotions to move towards stress free joyful state of mind. Since most patients with CLBP have a component of psychological stress, these practices are relevant to correct the problem in a holistic way.

**Cyclic meditation:** This has includes a combination of both stimulating and relaxing or calming practices (Nagendra & Nagarathna 1997) its basis from traditional texts (Chinmayananda, 1984). Studies on this meditation have shown that this technique, which is a combination of yoga postures interspersed with relaxation, reduces arousal more than relaxation alone (Telles, Reddy & Nagendra, 2000).

**Yogic counseling:** Individual yogic counseling for stress management was focused on ‘happiness analysis’ from an ancient text called *Taittirīya Upaniṣad* which is similar to the CBT used in modern psychotherapy. This was used to help the patient with LBP to become aware of the emotional responses and restore their freedom to change these responses to chronic pain resulting in stress reduction.

**Mind sound resonance technique (MSRT):** Perception of the internal resonance of all tissues of the body during prolonged slow chanting of vedic syllables (a, u, m and Om etc) at very low pitch can help in the achieving a deep meditative state. Repeated practices of these syllables have been incorporated into this thirty-minute practice (Lokeswarananda, 1996).
5.9.2 **Control intervention**

The practices consisted of a set of standard physiotherapy practices for low back pain (certified by the senior physiatrist – Table 3 in the appendix), non-yogic safe breathing exercises, lectures on scientific information including (a) causes of back pain, (b) stress and CLBP and (c) the benefits of physical exercises. Video shows on animals, plants, nature etc. were used as placebo to engage them during the time when there was video show on yoga or yogic counseling for the experimental group.

| Table 5.3 - Matching of Practices for Yoga and Control |
|-----------------------------|-----------------------------|
| **Yoga Group**               | **Control Group**            |
| 1. Meditation               | Walking                     |
| 2. Yoga-based physical practices - Āsanas | Physiotherapy based exercises |
| 3. Chanting of Yogic Hymns | Video show on nature        |
| 4. Lectures on Yogic lifestyle – Yoga philosophy, Yogic way of life, Yogic concept of stress, Yogic management of backpain etc | Lectures on healthy lifestyle – Stress and back pain, causes of back pain, benefits of physiotherapy for back pain, healthy lifestyle etc. |
| 5. Prāṇāyāma               | Non-Yogic breathing practices |
| 6. Relaxation Technique     | Rest in the room.            |
| 7. Assesments and Counselling | Assesments and Counselling   |
| 8. Cyclic Meditation        | Listening to music           |
| 9. Bhajans                  | Video show on nature         |
| 10. Meditation with Yogic chants | Walking                    |