5 METHODOLOGY

5.1 Subjects

88 female nursing professionals with chronic low back pain of age range 24-40 years willing to participate in the study were recruited

5.2 Source of Subject

Female nursing professionals of R L Jalappa hospital and research center Tamaka, Kolar, India, (A Tertiary care teaching hospital) who fulfill the inclusion and exclusion criteria, were recruited.

5.3 Sample Size

The calculated sample size was 88 (44 in each group)

In the present study we have used multiple parameters from different domains (pain disability, quality of life and psychological) of chronic low back pain. As the parameters used in the study were diversified, statistician suggested to calculate sample size for following three domains separately by using the effect size of earlier studies and consider the highest sample size among three for the present study.

> 1. Pain and disability,
>
> 2. Quality of Life and
>
> 3. Psychological parameters (stress, anxiety, depression etc.)

Calculation of sample size for Pain and Disability: A sample size of 36 was calculated by using non-commercial statistical power analysis program 'G*'Power software, version 3.0.10, keeping an effect size of 1.26, an α level at 0.05 and power at 0.95. This effect size of 1.26 was obtained by using the mean and SD of the Oswestry

Disability Index, measures from an earlier interventional study that used Yoga lifestyle program (Tekur et al., 2008).

Same method was repeated by using effect size of earlier studies for Quality of life and Psychological parameters separately and found sample size of 28 and 70 respectively.

This provided us the sample size of 36, 28 and 70 for Disability, QoL & Psychological parameters respectively. To allow for a 20 to 25% of dropouts statistician recommended the sample size of 88 (44 in each group) for the present study.

Following is the screen shot sample size calculation for pain and disability by using 'G*'Power software, version 3.0.10.
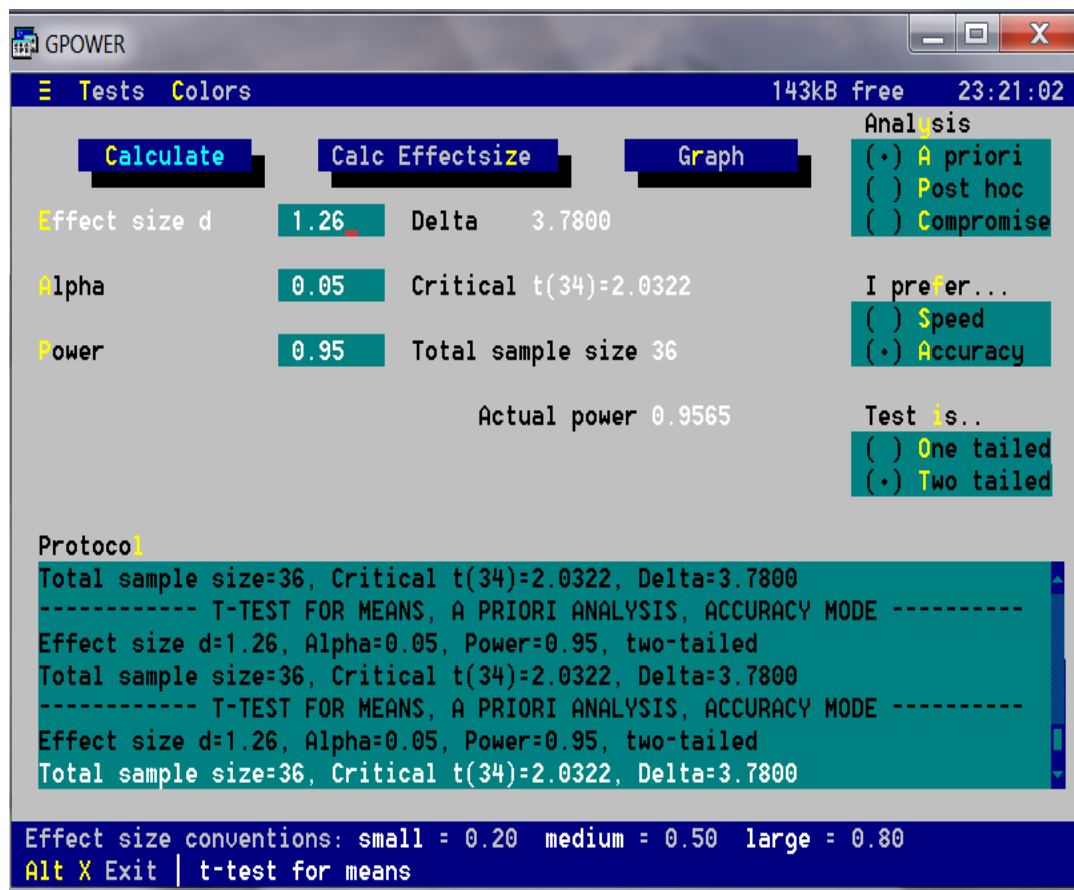

Figure 5.3.3. Snapshot of Sample size calculation (G* Power software)

5.4 Randomization

88 random numbers having 1 and 2 digits (44 each) were generated by using www.randomizer.org. Patients were recruited to as per the following table. '1' number patients were recruited to yoga group (YG) and '2' number were recruited to control group (CG).

Table 5.4-1. Random number table

> 1, 2, 1, 2, 2, 2, 2, 2, 1, 2, 1, 2, 1, 1, 1, 2, 1, 2, 1, 2, 1, 1, 2, 1, 1, 1, 2, 1, 1, 2, 1,
>
> 2, 1, 1, 1, 2, 1, 1, 2, 2, 1, 2, 1, 2, 2, 1, 2, 2, 2, 1, 2, 2, 1, 2, 1, 2, 1, 1, 2, 2, 1, 1,
>
> 2, 1, 2, 2, 1, 1, 1, 2, 1, 1, 1, 1, 2, 1, 1, 2, 2, 2, 2, 2, 2, 1, 2, 2, 1, 2

> '1'- YG
> '2' - CG

Where '1' – yoga group (YG) ; '2'-control group (CG).

All outcome measures were assessed at baseline and after six weeks of interventions. Assessments were carried out by persons who are not involved in the interventions / teaching to nullify the confounding investigator bias variable.

5.5 Design of the study

It was a prospective randomized control trial. Experimental group received integrated yoga Therapy Module (IYTM) and control group was intervened with physical exercises.
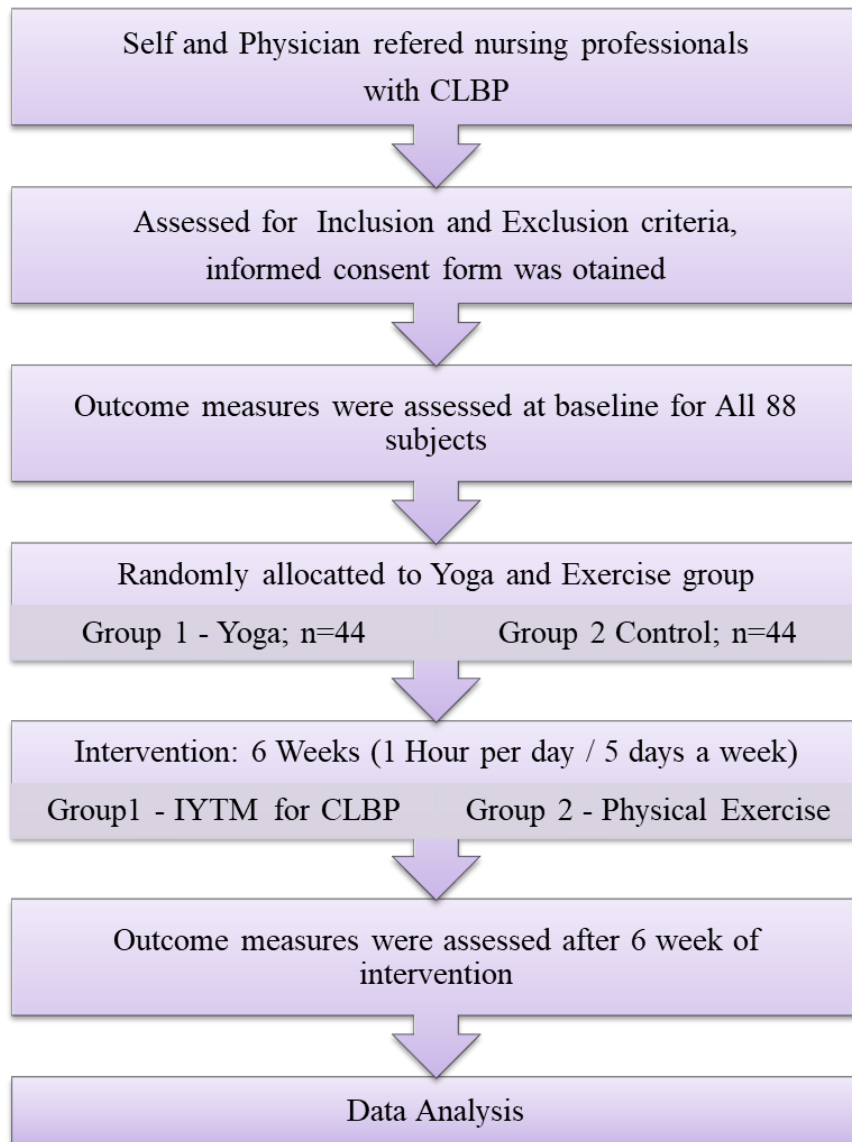
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┌─────────────────────────────────────────────┐
│   Self and Physician refered nursing          │
│   professionals with CLBP                      │
└─────────────────────────────────────────────┘
                     ↓
┌─────────────────────────────────────────────┐
│   Assessed for Inclusion and Exclusion         │
│   criteria, informed consent form was otained  │
└─────────────────────────────────────────────┘
                     ↓
┌─────────────────────────────────────────────┐
│   Outcome measures were assessed at baseline   │
│   for All 88 subjects                          │
└─────────────────────────────────────────────┘
                     ↓
┌─────────────────────────────────────────────┐
│   Randomly allocatted to Yoga and Exercise     │
│   group                                        │
│   Group 1 - Yoga; n=44    Group 2 Control; n=44│
└─────────────────────────────────────────────┘
                     ↓
┌─────────────────────────────────────────────┐
│   Intervention: 6 Weeks (1 Hour per day / 5    │
│   days a week)                                 │
│   Group1 - IYTM for CLBP   Group 2 - Physical  │
│                             Exercise           │
└─────────────────────────────────────────────┘
                     ↓
┌─────────────────────────────────────────────┐
│   Outcome measures were assessed after 6 week  │
│   of intervention                              │
└─────────────────────────────────────────────┘
                     ↓
┌─────────────────────────────────────────────┐
│   Data Analysis                                │
└─────────────────────────────────────────────┘
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Figure -5.Trail Profile

5.6 Inclusion and Exclusion criteria

CLBP is having wide range of causative and risk factors. CLBP in labor, who involved building construction work, is more of physical, the CLBP in software engineers will be more of psychological. In case of nursing professionals it's both physical, psychological. This made us restrict present study to nursing professionals.

Inclusion criteria:

- Age: 24 to 40 years.

- Gender: Female

- History of Low back pain for more than 3 months.

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

Exclusion criteria

- Organic spinal pathology such as malignancy, tuberculosis.

- Recommended surgical intervention

- Severe obesity, Pregnant, Gynecological diseases, Critically ill

- Who are on medications such as anticholinergic (including antidepressants, antihistaminics, anti- coagulants, analgesics and steroids)

- Who are practicing Yoga / exercise regularly in the previous three months

5.7   Semi structured interview schedule

Medical assessment was conducted by orthopedic surgeon. A semi-structured interview was used to obtain both demographic and vital clinical data, including personal, family and stress history. (Patient case preform is attached in annexure)

Ethical clearance and informed consent: Before taking up the study, ethical clearance was obtained by the institutional ethical committee (IEC) (Ref No. Res./IEC-SVYASA/16/2013 dated 25th February 2014) of SVYASA Yoga University, Bengaluru. IEC certificate attached in annexure)

Signed, informed consent was obtained from all subjects who participated in the study before recruiting. Informed consent form is attached in annexure.

5.8   Specific outcome measures /variables

Following specific outcome measures were assessed at baseline and after 6 weeks of intervention

Table 5.8-1. Specific outcome measures

Category	Name of the Scale
Pain and Disability Scale	1. Numerical Rating Scale for pain. (NRS)
	2. Roland Morris Disability Questionnaire (RMDQ)
Psychological Variables.	3. Fear Avoidance Belief Questionnaire (FABQp, FABQw)
	4. State –Trait Anxiety Inventory (STAI)
	5. Beck Depression Inventory (BDI)
	6. Perceived Stress Scale (PSS)
Objective assessment of Autonomic Nervous system (ANS)	7. Heart Rate Variability (HRV)
Quality of Life Scale	8. WHO Quality of Life Scale – Brief Version (WHOQOLBREF)

A. Measures of Disability and pain.

1. Numerical Rating Scale for pain. (NRS):

This is 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 (Jensen et. al. 1986).

2. Roland Morris Disability Questionnaire (RMDQ):

The Roland-Morris Questionnaire (RMQ) is a self-administered disability measure in which greater levels of disability are reflected by higher numbers on a 24-point scale. Recall period for items relates to the last 24 hours. The items represent the execution

of daily physical activities and functions that may be affected by LBP, such as housework, sleeping, mobility, dressing, getting help, appetite, irritability, and pain severity. The RMQ has been shown to yield reliable measurements, which are valid for inferring the level of disability, and to be sensitive to change over time for groups of patients with low back pain. (RMDQ Scores range from 0 (no disability) to 24 (maximal disability).It takes approximately 5 minutes to complete (Roland et al., 1983; 2000).

B. Psychological Variables.

3. Fear Avoidance Belief Questionnaire:

The emergence of the biopsychosocial model of low back pain (LBP) led Waddell et al to develop the Fear Avoidance Beliefs Questionnaire (FABQ). The FABQ Reliability and validity tool to assess patient beliefs with regard to the effect of physical activity and work on their LBP. It consists of 16 items and patients rate their agreement with each statement on a 7-point Likert scale (0 = completely disagree, 6 = completely agree). The original factor analysis revealed two subscales: the work subscale (FABQw) with 7 questions (maximum score = 42) and the physical activity subscale (FABQpa) with 4 questions (maximum score = 24). A higher score indicates more strongly held fear avoidance beliefs. It takes approximately 10 minutes to complete (Waddell et al., 1993).

4. State –Trait Anxiety Inventory (STAI):

STAI developed by Spiel Berger et al consists of 2 forms (Y1 and Y2) each comprising of 20 items. All items are rated on a 4-point scale (e.g., from "Almost Never" to "Almost Always"). Higher scores indicate greater anxiety. Its reliability

and validity is proved beyond doubt. It has been extensively used in the Indian context and found to be useful.

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'. It evaluates how the respondents feel right now at this moment.State anxiety items include: "I am tense; I am worried" and "I feel calm; I feel secure."

Form Y2 evaluates trait anxiety, which is 'a relatively stable individual predisposition to respond to situations perceived as threatening'. Trait anxiety items include: "I worry too much over something that really doesn't matter" and "I am content; I am a steady person" (Spielberger et al., 1989).

5. **Beck Depression Inventory (BDI):**

BDI is a 21 item inventory devised by Beck et al, 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.

6. Perceived Stress Scale (PSS):

The Perceived Stress Scale (PSS) (Cohen et al., 1983) is the most widely used psychological instrument for measuring the perception ofstress. It is a measure of the degree to which situations in one's life are appraised as stressful. Items were designed to tap how unpredictable, uncontrollable, and overloaded respondents find their lives. The questions in the PSS ask about feelings and thoughtsduring the last month. In each case, respondents are asked how often they felt a certain way.PSS has adequate internal test and retest reliability (Cohen et al., 1983).

Scoring: Each item is rated on a 5-point scale ranging from never (0) to almost always (4). Positively worded items are reverse scored, and the ratings are summed, withhigher scores indicating more perceived stress.PSS-10 scores are obtained by reversing the scores on the four positive items: For example, 0=4, 1=3, 2=2, etc. and then summing across all 10 items.Items 4, 5, 7, and 8 are the positively stated items

Norm Table for the PSS 10 item inventory			
Category		Mean	S.D.
Gender	Male	12.1	5.9
	Female	13.7	6.6
Age	18-29	14.2	6.2
	30-44	13.0	6.2
	45-54	12.6	6.1
	55-64	11.9	6.9
	65≥	12.0	6.3

C. Objective assessment of Autonomic nervous system

7. Heart Rate Variability (HRV):

HRV is a non-invasive technique for recording heart rate variability (Berntson et al., 1997; Evans et al., 2013). Heart rate is the number of heart beats per minute. Heart

rate variability (HRV) is the fluctuation in the time intervals between adjacent heartbeats. HRV indexes neurocardiac function and is generated by heart-brain interactions and dynamic non-linear autonomic nervous system (ANS) processes. HRV reflects regulation of autonomic balance, blood pressure (BP), gas exchange, gut, heart, and vascular tone. HRV commonly reported in terms of frequency domain and time domain.

HRV was recorded byusing AD instrument_ HRV module7_ Model ML818, which is reliable and valid instrument and widely used in the physiology labs across the globe.

Procedure: Following instructions are given to the subjects:

a. Subject should not have coffee, nicotine or alcohol 24 hours prior to testing

b. Avoid meals preceding 2 hours of the testing

c. Wear comfortable and loose clothing.

Recording: For short term analysis of HRV, 5 minute ECG was recorded in the study participants using the (AD Instruments) hardware and Power Lab (AD Instruments) software in supine position after 15 minutes of supine rest on a bed. All recordings were done between 9am to 1pm in a light and noise minimized room in the department and a room temperature of 24 to 27°C was maintained for all the recordings. Subject was asked to close the eyes, avoid talking, avoid moving hands, legs or body and avoid sleeping during test.

D. Quality of Life Scale

8. 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. There are also two items that are examined separately: question 1 asks aboutan individual's overall perception of quality of life and question 2 asks about an individual's overallperception of their health. 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. It is having with good to excellent psychometric properties of reliability and validity. Higher values indicate better QOL. (WHOQOL Group, 1998; Skevington et al., 2004).

General variables

9. Blood Pressure (mm of Hg):

Blood Pressure was recorded daily by a qualified nurse on the right arm in sitting position using a mercury sphygmomanometer (Diamond Company, India).

10. Pulse rate (beats per minutes):

Pulse (number of beats per minute) was noted daily by a qualified nurse manually at the right radial artery in sitting position by using a mercury sphygmomanometer (Diamond Company, India) and stopwatch.

11. Respiration rate:

The resting respiration rate (RR cycle per minute) was noted by visual observation of the respiratory movements of the abdomen or the chest wall while the participant was seated. R R was also noted by qualified nursing professional.

12. *Bhramari* time (BHT in seconds):

BHT 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 ***Bhramara*** 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.

13. Body Mass Index (BMI):

The body mass index (BMI) is a value derived from the body weightand height of an individual. The BMI is defined as the body weight in kilogram divided by the square of the body height in meter. It is universally expressed in units of kg/m2. Following table shows nutritional status based on the WHO and Asian criteria values.

Table 1: Nutritional status based on the WHO and "Asian criteria" values		
Nutritional Status	WHO criteria BMI cut-off	"Asian criteria" BMI cut-off
Underweight	<18.5	<18.5
Normal	18.5 – 24.9	18.5 – 22.9
Overweight	25 – 29.9	23 – 24.9
Pre-Obese	-	25 – 29.9
Obese	≥30	≥30
Obese Type 1 (obese)	30 – 40	30 – 40
Obese Type 2 (morbid obese)	40.1 – 50	40.1 – 50
Obese Type 3 (super obese)	>50	>50

5.9   Intervention

The 88 subjects were recruited randomly into two (Yoga and Control) groups. Study group received integrated Yoga and control group received physical exercises for period of six weeks (one hour per day, 5 days a week). The pre and post assessments were carried out by persons who were not involved in teaching or counseling the subjects to nullify the confounding investigator bias variable.

a. Yoga group (YG): Integrated Yoga (Patil et al., 2012) consists of selected loosening exercises, Yogasanas (Postures), Pranayama (Breathing exercises), Relaxation technique and Yogic counselling.

b. Control group (CG): Physiotherapeutic exercises breathing exercises and counseling. Detailed list of practices of the both group are listed in Table no 5.9.1. below

Table 5.9-1. List of Practices in Yoga and Control (Exercise) group

List of Practices for Yoga Group	List of practices for Control Group
Supta udarakarshanasana (folded leg lumbar stretch)	Standing hamstring stretch
Shava udarakarshanasana (crossed leg lumbar stretch)	Cat and Camel
Pavanamuktasana (wind releasing pose)	Pelvic tilt
Setu bandhasana breathing (bridge pose lumbar stretch)	Partial curl
VyaghraSana (tiger breathing)	Piriformis stretch
Bhujangasana (serpent pose)	Extension exercise
Shalabhasana breathing (locust pose)	Quadriceps leg raising
Uttanapadasana (straight leg raise pose)	Trunk rotation
Ardha kati chakrasana (lateral arc pose)	Double knee to chest
Ardha chakrasana (half wheel pose)	Bridging
Quick relaxation techniques	Hook lying march
Nadi shuddhi (alternate nostril breathing)	Single knee to chest stretch
Bhramari (humming bee breath)	Lumbar rotation
Nadanusandhana (A, U, M, AUM chanting)	Press up
Deep relaxation technique	Curl ups

Detailed instructions along with pictures of integrated Yoga and physiotherapy exercises were provided in an annexure 12.5